

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

	x	
	:	
THE CITY OF HUNTINGTON,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01362
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

	x	
	:	
CABELL COUNTY COMMISSION,	:	Civil Action
	:	
Plaintiff,	:	No. 3:17-cv-01665
	:	
v.	:	
	:	
AMERISOURCEBERGEN DRUG	:	
CORPORATION, et al.,	:	
	:	
Defendants.	:	

BENCH TRIAL - VOLUME 23
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

JUNE 9, 2021

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Proceedings recorded by mechanical stenography;
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1 PROCEEDINGS had before The Honorable David A.
2 Faber, Senior Status Judge, United States District
3 Court, Southern District of West Virginia, in
4 Charleston, West Virginia, on June 9, 2021, at 9:00
5 a.m., as follows:

6 THE COURT: Mr. Fuller, you have something you
7 want to bring up?

8 MR. FULLER: Judge, just real briefly. We had
9 previously admitted P-14288 that didn't have page numbers on
10 it and it is a voluminous document, so we're going to
11 substitute in, with the Court's permission, a paginated
12 version.

13 And then P-14290, these are Cardinal's policies and
14 procedures. Cardinal has no objection and the clerk said it
15 was okay to give it to her on a thumb drive because it's
16 voluminous, if that's all right with the Court.

17 THE COURT: Okay. You may do so, Mr. Fuller.

18 MR. FULLER: Thank you, Judge.

19 THE COURT: I have what I think will be welcome
20 news. In consultation with the Chief Judge and the Clerk of
21 Court, I'm authorized to tell you that fully vaccinated
22 individuals can go without masks while in the courtroom.

23 (Applause)

24 THE COURT: In this courtroom. And you still have
25 to comply with the mask order while in common areas and

1 maintain the occupational limits that were put in place at
2 the beginning of the trial and these rules are being
3 constantly re-evaluated, I'm told, but at least while you're
4 in this courtroom, you don't have to wear the masks.

5 SIMULTANEOUS SPEAKERS: Thank you, Your Honor.

6 THE COURT: So, I'm no longer setting a bad
7 example.

8 (Laughter)

9 THE COURT: Also, I'm struggling about the time
10 limitations on the court and I am trying to work through a
11 proposal for you on that, but for now, unless somebody has
12 travel plans that are going to be totally disrupted by this,
13 we will go until 5:00 on Friday. Is that a problem with
14 anybody? I see no -- okay.

15 And I'm trying to figure out a way to maybe allow a
16 little more time without disrupting the trial schedule, but
17 I'll try to have a proposal to you for that shortly.

18 Are we ready to go with Mr. Rannazzisi?

19 Are you in the courtroom, sir?

20 MR. SCHMIDT: May I take the podium, Your Honor?

21 THE COURT: Yes.

22 MR. SCHMIDT: Thank you.

23 THE COURT: And, Mr. Rannazzisi, you don't have to
24 wear the mask anymore in this courtroom, but you have to
25 follow all the other rules that are in place.

1 THE WITNESS: Thank you very much, Judge. That's
2 great.

3 THE COURT: The abominable masks.

4 THE WITNESS: And good morning, Your Honor.

5 THE COURT: Good morning, sir.

6 You may proceed, Mr. Schmidt.

7 MR. SCHMIDT: Thank you, Your Honor.

8 Good morning, Mr. Rannazzisi.

9 THE WITNESS: Good morning.

10 MR. SCHMIDT: Good morning again, Your Honor.

11 May I approach?

12 BY MR. SCHMIDT:

13 **Q.** Mr. Rannazzisi, I'd like to turn next to some of your
14 testimony from the past two days about the suspicious order
15 reporting process and I want to start with what I've passed
16 you as DEF-WV-640. Do you recognize this as including the
17 suspicious order regulation from the DEA website?

18 **A.** Yes.

19 MR. SCHMIDT: I don't think we've previously moved
20 this into evidence. I'll go ahead and do that. DEF-WV-640.

21 THE COURT: Any objection?

22 MR. ACKERMAN: No objection.

23 THE COURT: It's admitted.

24 BY MR. SCHMIDT:

25 **Q.** So, what I'd like to do, Mr. Rannazzisi, is could we

1 cull out Subsection (b), as in boy? Do you recognize this
2 as the relevant suspicious order regulation?

3 **A.** Yes.

4 **Q.** And it says the registrant shall design and operate a
5 system to disclose to the registrant suspicious orders of
6 controlled substances. The registrant shall inform the
7 Field Division Office of the administration in his area of
8 suspicious orders when discovered by the registrant. And
9 then here's the language I want to focus on. Suspicious
10 orders include orders of, and can we underline unusual size
11 or highlight it, and then orders, quote, "deviating
12 substantially from a normal pattern", and, quote -- and
13 orders of, quote, "unusual frequency". Do you see that?

14 **A.** Yes.

15 **Q.** And these three criteria that we've highlighted are the
16 only criteria specified in this regulation, unusual size,
17 deviating substantially from a normal pattern, unusual
18 frequency, correct?

19 **A.** That is correct, yes.

20 **Q.** You talked over the past couple days about something
21 you refer to as truly suspicious. Is -- when you were
22 talking about something that is truly suspicious, is that
23 something different than a company making a judgment in
24 their view that an order is of unusual size, deviating
25 substantially from a normal pattern, or unusual frequency?

1 Is there any difference between those two, just yes or no,
2 if you can?

3 **A.** No. There's no difference.

4 **Q.** In fact -- and there's no greater -- let me try it this
5 way. When you were at DEA you told companies that in terms
6 of interpreting what this language means, in terms of
7 applying it, DEA cannot tell a distributor if an order is
8 suspicious under these criteria, correct?

9 **A.** It was up to the distributor to make the decision
10 whether an order is suspicious or not, yes.

11 **Q.** And you told them DEA cannot tell a distributor if an
12 order is suspicious, true?

13 **A.** Yes, that's true.

14 **Q.** It was up to them?

15 **A.** Yes.

16 **Q.** And in terms of DEA itself, DEA had no internal
17 guidance for what is a suspicious order, correct?

18 **A.** There was no guidance except for the regulation, yes.

19 **Q.** On your watch as Head of Diversion Control from 2005 to
20 2015, DEA never had internal guidance as to what constituted
21 a Suspicious Order Monitoring System that complied with
22 regulations, correct?

23 **A.** Yes, that is correct.

24 **Q.** Are you aware that DEA has proposed to amend this
25 regulation?

1 **A.** I believe that -- I don't know what DEA is doing, but I
2 believe that Congress actually codified that regulation.

3 **Q.** Do you know if DEA has proposed a rule making process
4 to amend this regulation?

5 **A.** I don't know.

6 **Q.** Okay. You talked about having responsibility for
7 promulgating regulations, correct?

8 **A.** That's correct.

9 **Q.** You never amended this regulation on your watch, did
10 you?

11 **A.** No, I did not.

12 **Q.** Did you ever try internally to add language to this
13 regulation that would go to any of the points you've talked
14 about in your testimony, do not ship, explain why an order
15 is being reported, only report truly suspicious? Did you
16 ever attempt internally to amend the regulation on any of
17 those grounds?

18 **A.** No, I did not.

19 **Q.** Now, I want to come to an idea I just touched on, which
20 is do you remember talking about explaining -- distributors
21 explaining why suspicious orders were being reported? Do
22 you remember giving --

23 **A.** Can you repeat that one more time?

24 **Q.** Sure. You gave testimony on several times that you
25 weren't getting explanations for why suspicious orders were

1 being reported. Do you remember saying that?

2 **A.** Yes.

3 **Q.** And I'll come back to what the distributors actually
4 did explain, but before I do that, I want to go to this
5 regulation as left unamended by you. There's no language in
6 this regulation saying explain why you consider it to be of
7 unusual size, deviating substantially from a normal pattern,
8 or of unusual frequency, correct?

9 **A.** That is correct.

10 **Q.** And you never sought to amend the regulation to require
11 such an explanation, correct?

12 **A.** We did not amend the regulation, that's correct.

13 **Q.** All right. I want to follow up on testimony you had
14 about there not being any policy change at DEA when you came
15 into place and I want to focus on this 2005 to 2008 window,
16 if that's okay.

17 **A.** Okay. Yes, sir.

18 **Q.** And do you have the understanding that, as the Court
19 has heard through testimony, by 2008 every defendant in this
20 case had a policy in place that involved blocking flagged
21 orders? Do you have that understanding?

22 **A.** From my knowledge at DEA?

23 **Q.** Yes, sir.

24 **A.** Yes.

25 **Q.** Okay. And you agree that if an order is blocked the

1 medicine cannot be diverted?

2 **A.** If the order is blocked, the medicine can't go
3 downstream.

4 **Q.** And it can't be diverted, correct?

5 **A.** That's correct.

6 **Q.** And from your time at DEA you can't identify any orders
7 in Huntington or Cabell County that you believed that DEA
8 should have been blocked by one of the defendants but were
9 not, correct?

10 MR. ACKERMAN: Objection, Your Honor, and this
11 goes to the scope of Mr. Rannazzisi's deposition. The words
12 "West Virginia" don't appear in the deposition transcript,
13 so --

14 THE COURT: Overruled. This is cross examination.
15 I'll allow it. Go ahead.

16 THE WITNESS: No, I have not reviewed any
17 documents related to West Virginia.

18 BY MR. SCHMIDT:

19 **Q.** So, let me focus still on this time period when you
20 came in from 2005 through 2008 and even into 2009. Am I
21 correct that before 2006 and 2007 you have no firsthand
22 knowledge about whether the DEA was aware that it had
23 earlier been standard practice in the industry to file
24 Suspicious Order Reports while continuing to ship product?
25 Am I correct you have no firsthand knowledge on that point?

1 **A.** Could you -- what do you feel is firsthand knowledge?

2 **Q.** Whatever you consider firsthand knowledge. And if it
3 helps to show you your testimony, I can show you your
4 testimony.

5 **A.** I have no -- I have no direct knowledge except for what
6 my staff told me.

7 **Q.** And I'm not going to ask you about discussions because
8 of hearsay. You've talked about effective controls against
9 diversion; you remember that, right?

10 **A.** Yes.

11 **Q.** Am I correct that prior to the Fall of 2005 and since
12 1970, you can't recall any type of document or guidance
13 where the distributors were told to do certain things that
14 were related to maintaining effective controls against
15 diversion?

16 **A.** That's correct.

17 **Q.** And am I correct you've not watched the testimony in
18 this case to see testimony from individual witnesses at
19 individual companies where they said prior to 2008 if they
20 saw something that they thought was likely to be diverted
21 they would block it? Have you seen that testimony?

22 **A.** I have not seen that testimony, no.

23 **Q.** Do you know what the practice was prior to 2005 with
24 the defendants in this case when they saw an order that was
25 likely to be diverted?

1 **A.** I only know what I was briefed on at the time, yes.

2 **Q.** For example, did you review McKesson's Section 55 of
3 this Drug Operation Manual to see that practice of blocking
4 orders that were actually likely to be diverted before 2008
5 codified in the manual? Have you reviewed the manual to see
6 that?

7 **A.** When I was with DEA?

8 **Q.** Yes, sir.

9 **A.** No, I didn't review the manual but, again, I was
10 briefed on that before the Orders to Show Cause were issued.

11 **Q.** Do you remember being briefed on that provision of the
12 manual?

13 **A.** I was briefed on the overall -- the overall system
14 before the -- before the Order to Show Cause was issued. I
15 was briefed on the overall system.

16 **Q.** That included a portion of McKesson's manual that
17 codified the practice of blocking orders that actually
18 appeared like they were likely to be diverted before 2008?

19 **A.** I don't recall the specific provisions that I was
20 briefed on.

21 **Q.** Let's look at your 2006 letter, please. Do you
22 recognize this as your September 27, 2006 letter?

23 **A.** Yes.

24 **Q.** And if we go to Page 2, I want to pick up on a sentence
25 you were asked about.

1 **A.** Okay.

2 **Q.** In the second paragraph, the first sentence, DEA
3 recognizes that the overwhelming majority of registered
4 distributors act lawfully and take appropriate measures to
5 prevent diversion. Did you believe that statement to be
6 true when you said it in September of 2006?

7 **A.** Yes.

8 **Q.** You don't know of any distributor that was blocking
9 suspicious orders instead of shipping them and reporting
10 before 2008, correct?

11 **A.** Could you repeat that one more time?

12 **Q.** Of course I can. You don't know of any distributor
13 that was blocking suspicious orders instead of shipping them
14 and reporting them before 2008, correct?

15 **A.** Blocking suspicious orders before shipping and
16 reporting them? Well, if they were blocking them, they
17 wouldn't be shipping them. So, no, I don't know of anybody.

18 **Q.** In place of? Do you know of any distributor that was
19 blocking suspicious orders instead of shipping and reporting
20 them before 2008?

21 **A.** I don't believe -- no, I don't, because they were
22 continuing to ship downstream.

23 **Q.** Okay. And you don't know whether it's true or false
24 that no distributor blocked suspicious orders before sending
25 them prior to 2006 when you wrote this letter that you

1 recognize that the overwhelming majority of registered
2 distributors act lawfully, correct?

3 **A.** We weren't receiving suspicious orders back then.

4 **Q.** Well, I'm going to come to that point. I'm asking you
5 a separate question, sir.

6 **A.** Okay.

7 **Q.** No distributor blocked suspicious orders before sending
8 them prior to 2006? You don't know if that's true or false,
9 do you?

10 **A.** I don't know if it's true or false.

11 **Q.** You can't point to any action the DEA took against any
12 of the hundreds of distributors that were reporting and
13 shipping prior to 2006, correct?

14 **A.** I don't recall any actions prior to 2006.

15 **Q.** You mentioned Michael Mapes several times. He was one
16 of your colleagues at the DEA, correct?

17 **A.** Yes.

18 **Q.** And, in fact, he was responsible for training diversion
19 investigators when you joined DEA, correct?

20 **A.** Yes, he was.

21 **Q.** He oversaw the program that trained you as a diversion
22 investigator, correct?

23 **A.** Yes.

24 **Q.** And you have seen testimony where he said he told the
25 plaintiff lawyers in front of you that DEA accepted

1 companies shipping and then reporting suspicious orders,
2 correct?

3 **A.** I saw what he said.

4 **Q.** Yes.

5 **A.** It was presented to me in my deposition, but I didn't
6 agree with that.

7 **Q.** I understand you don't agree with that, but you had
8 seen his testimony?

9 **A.** Yes.

10 **Q.** Before it was presented to you, correct?

11 **A.** I don't recall seeing his testimony before it was
12 presented to me in deposition, no.

13 **Q.** Let's cull up the July 16th, 2020 transcript and I'll
14 show you what I'm talking about and, if I'm misunderstanding
15 what you're saying, you can tell me. Page 210, Line 1 to 7,
16 please.

17 Do you see where I had the chance to ask you -- Line 1
18 to 7, please. Did you see that in his testimony that he
19 told plaintiff lawyers, including lawyers in this case, and
20 this is a different case, that DEA accepted companies
21 shipping and then reporting suspicious orders? Did you see
22 that in his testimony? Answer, I saw that in his testimony.

23 **A.** Can I see what was done before that?

24 MR. ACKERMAN: Your Honor --

25 THE WITNESS: Can I see the page before that, Page

1 209?

2 MR. ACKERMAN: Mr. Schmidt, can you give me the
3 date of that deposition again?

4 MR. SCHMIDT: Yes. It's July 16th, 2020.

5 THE WITNESS: I don't want this taken out of
6 context, so if I could look at 209, that would be great.

7 BY MR. SCHMIDT:

8 **Q.** My testimony is, do you see that testimony?

9 MR. ACKERMAN: Your Honor, before we go forward,
10 is that the MDL deposition or is that Mr. Rannazzisi's
11 expert deposition in a different case?

12 MR. SCHMIDT: It's the Ohio deposition.

13 MR. ACKERMAN: So, Your Honor, this is -- I need
14 to make a record on this. The defendants filed a motion
15 that said the scope of Mr. Rannazzisi's testimony is limited
16 to information that was in his MDL depositions and we, the
17 plaintiffs, agreed to that and that was the scope of the
18 direct questioning. And when we went outside that scope,
19 defendants objected.

20 This line of questioning is now concerning something
21 that wasn't in the MDL deposition, but was in a totally
22 separate expert deposition in another case involving the
23 Ohio Attorney General. So, we would object to this line of
24 questioning as outside the scope because cross examination
25 necessarily has to be within the scope of the direct

1 examination.

2 MR. SCHMIDT: Two responses, Your Honor. This is
3 within the scope. He testified about there not being a
4 change in policy. He knows there was testimony from his
5 colleagues, the very person who trained him, that there was
6 a change in policy. So, that's an appropriate question
7 that's well within the scope even if we were limited to the
8 scope of his exam, which I don't believe we are. We're with
9 a fact witness who we can't re-call in our case; but even if
10 we were, it's well within the scope.

11 And as to the point that this is from an expert
12 deposition, yes, it is, but this question is about his
13 knowledge, the expertise he's claiming from being a DEA
14 servant.

15 I'm not going to ask him about any of his expert
16 opinions in Ohio because I agree those are off limits, but
17 when he made factual statements, or talked about his
18 experience, or talked about his knowledge, it's not a
19 get-out-of-jail-free card where that's not usable. That's
20 sworn testimony. And it's based on his experience, not
21 based on his expert opinions in that case.

22 THE COURT: Well, this is cross examination and
23 this is a prior statement that appears to be potentially
24 inconsistent and I think it's fair game, Mr. Ackerman, and
25 I'll overrule your objection.

1 BY MR. SCHMIDT:

2 Q. Do you remember showing the judge the Diversion
3 Investigators Manual from 1997, Mr. Rannazzisi?

4 A. Yes.

5 Q. I want to come back to that. Can we put that up on the
6 screen? It's P-8861, Page 10. And do you still -- if you
7 need a copy, I can give you a second to find it, but I'm
8 going to show you exactly on the screen what we're looking
9 at. It's Page 10 of P-8861. Do you recognize this as the
10 Diversion Investigators Manual?

11 A. I recognize it as the Diversion Investigators Manual.
12 I don't have it in front of me.

13 MR. SCHMIDT: May I approach, Your Honor?

14 THE COURT: Yes.

15 Q. It's got a cover e-mail that looks like this. That's
16 not going to be it. It's a half page cover e-mail. But I'm
17 going to show it to you on the screen, so only if you need
18 it.

19 A. Okay.

20 MR. SCHMIDT: And while we're looking for that,
21 can we go to the next page, please, and highlight the date
22 of this document at the bottom?

23 BY MR. SCHMIDT:

24 Q. Tell me when you're ready for me, Mr. Rannazzisi.

25 A. Here it is. We can just go off the screen. That would

1 be fine.

2 **Q.** Okay. Do you see on Page 11 this Diversion
3 Investigators Manual is dated April 16th, 1996?

4 **A.** Yes.

5 **Q.** And let's go to the language that you talked about
6 yesterday on the next page and I want to spend a little bit
7 more time on some of that language. Let's start with the
8 first full sentence on the page. It says suspicious orders
9 include those which are in excess of legitimate medical use
10 or exhibit characteristics leading to possible diversion
11 such as. Do you see that language?

12 **A.** Yes.

13 **Q.** And it then lists some of the criteria from -- or all
14 the criteria from the suspicious order regulation?

15 **A.** Yes.

16 **Q.** Unusual size, unusual frequency, or those deviating
17 from a normal pattern, correct?

18 **A.** Yes.

19 **Q.** And what this says is that might lead to possible
20 diversion, correct?

21 **A.** Yes.

22 **Q.** It then goes on to say how the supplier, the
23 distributor, can determine whether something is suspicious,
24 correct?

25 **A.** Yes.

1 Q. It says the supplier can determine whether an order is
2 excessive. Do you see that word excessive?

3 A. Yes.

4 Q. By checking their own sales and establishing the
5 average amount of controlled substances shipped to
6 registrants of the same apparent size in a particular
7 geographic area. Do you see that?

8 A. Yes.

9 Q. And so, that's talking about setting a threshold as a
10 means of identifying suspicious orders, correct?

11 A. It's one method, yes.

12 Q. And it's the only method listed here, correct?

13 A. Yes.

14 Q. It then says that in the next sentence. If the
15 customer exceeds this threshold, the request should be
16 viewed as suspicious. Do you see that?

17 A. Yes.

18 Q. And to be clear, if it's -- well, let me break this
19 down. This is saying that if a distributor sees orders that
20 exceed a threshold they've set for their customers that
21 should be viewed as suspicious, correct?

22 A. That's what it says, yes.

23 Q. And that means it should be reported, correct?

24 A. That means that customers should -- the distributors
25 should do due diligence to make the determination.

1 Q. It doesn't say due diligence anywhere in here, does it?

2 A. No, it does not.

3 Q. If an order is, quote, "viewed as suspicious", should
4 it be reported, yes or no?

5 A. According to this, yes.

6 Q. Okay. And then let's look at the next sentence,
7 please. And let me just start on the first two words. It
8 says this activity. Do you see those words, this activity?

9 A. Yes.

10 Q. This activity is an order that exceeds the threshold,
11 correct?

12 A. Yes.

13 Q. And it says this activity, and I want to focus on the
14 next clause, over extended periods of time. Do you see that
15 language?

16 A. Yes.

17 Q. Would lead a reasonable person to believe that
18 controlled substances possibly are being diverted. Do you
19 see that language?

20 A. Yes.

21 Q. And so, this is saying if you see this activity,
22 suspicious orders over extended periods of time, that
23 activity over extended periods of time would lead a
24 reasonable person to believe that controlled substances
25 possibly are being diverted, correct?

1 **A.** Yes.

2 **Q.** Now, there's no specific language in here saying that a
3 registrant should, quote, not fill a suspicious order,
4 correct?

5 **A.** I've got to read the rest of that.

6 **Q.** Take a moment. This is an important point, sir.

7 **A.** Well, it does later on in the paragraph.

8 **Q.** And what does it say?

9 **A.** As a general practice, investigation will be conducted
10 for possible violation of the CSA and regulations upon
11 determining that the reporting registrant, as a general
12 practice, does not voluntarily halt shipments of controlled
13 substances to registrants involved in suspected diversion or
14 to registrants against whom previous action has been taken.

15 **Q.** Okay. So, let's break that down because that's the
16 important point. First of all, it gives us two
17 circumstances for halting orders, correct?

18 **A.** Yes.

19 **Q.** One is where previous action has been taken against the
20 registrant, correct?

21 **A.** That's correct.

22 **Q.** And the other is registrants involved in suspected
23 diversion, correct?

24 **A.** Yeah.

25 **Q.** Those are the two instances where it says that -- where

1 it talks about voluntarily halting shipments, correct?

2 **A.** Yes.

3 **Q.** And let's talk about that second one, registrants
4 involved in suspected diversion. Do you see that language?

5 **A.** Yes.

6 **Q.** This tells us that seeing suspicious orders over
7 extended periods of time would lead a reasonable person to
8 believe that controlled substances are being diverted,
9 correct?

10 **A.** That's what it says, yes.

11 **Q.** There's no language in here that says that a company
12 should not fill a single suspicious order, correct?

13 **A.** I don't think we've ever taken action on a company that
14 filled a single suspicious order.

15 **Q.** Okay. And we looked at this language here about -- do
16 you see the reference to excessive in the context of talking
17 about setting thresholds as a trigger for reporting
18 suspicious orders?

19 **A.** Yes.

20 **Q.** There's no language in here that says Excessive
21 Purchase Reports will not be accepted, correct?

22 **A.** It won't have to because Excessive Purchase Reports
23 don't exist in the code or the regulations. Only Suspicious
24 Order Reports.

25 **Q.** When this talks about determining if an order is

1 excessive does it say anywhere in here Excessive Purchase
2 Reports will not be accepted? Does it say that, sir?

3 **A.** No. And, in fact, we did receive Excessive Purchase
4 Reports, but that's not a Suspicious Order Report.

5 **Q.** You've seen Mr. Mapes' sworn testimony where he said in
6 front of you that the DEA accepted Excessive Purchase
7 Reports as compliant with the Controlled Substances Act at
8 least between 1997 and the distributor briefings; true?

9 **A.** No. The first time I saw that was in my deposition in
10 the MDL. It was presented to me.

11 **Q.** Okay.

12 **A.** And I said during that deposition that I don't recall
13 that.

14 **Q.** Okay. But you have seen that testimony from Agent
15 Mapes, correct?

16 **A.** In my MDL deposition and I said that I didn't recall
17 him saying that. And during that meeting, I was in and out
18 of that meeting constantly because that was not my meeting.
19 I was there just to make an introduction.

20 **Q.** Totally fair. You just know he's testified to that,
21 right?

22 **A.** Yeah. After the MDL deposition.

23 **Q.** Okay. I want to look at this point we talked about, a
24 change in policy or not a change in policy. What is the
25 purpose of this Diversion Investigators Manual?

1 **A.** Diversion Investigators Manual provides guidance to
2 day-to-day operations and what they're supposed to be doing.

3 **Q.** What they're supposed to be doing? Okay. You changed
4 this very language we're looking at in the Diversion
5 Investigators Manual, correct?

6 **A.** I changed it?

7 **Q.** Uh-huh. Did you update the Diversion Investigators
8 Manual on your watch?

9 **A.** The Diversion Investigators Manual was updated, yes.

10 **Q.** All right. Let's take a look at that.

11 MR. SCHMIDT: I'm sorry, Your Honor. May I
12 approach? Thank you.

13 BY MR. SCHMIDT:

14 **Q.** So, I've given you DEF-WV-3842. It's a memorandum on
15 the DEA letterhead dated October 27th, 2009 from you with
16 your signature to various people, Special Agents in Charge,
17 Diversion Program Managers, Diversion ASACs, Diversion Group
18 Supervisors, TDS Supervisors. Do you recognize this
19 document with your signature on it?

20 **A.** Yes.

21 MR. SCHMIDT: We'd move this into evidence, Your
22 Honor, DEF-WV-3842.

23 THE COURT: Any objection?

24 MR. ACKERMAN: No objection.

25 THE COURT: It's admitted.

1 BY MR. SCHMIDT:

2 Q. All right. So, let's look at what we -- what this
3 document is doing. The first sentence of this document says
4 the Office of Diversion Control is in the process of
5 rewriting the diversion manual. That's the manual we were
6 just looking at, correct?

7 A. That's correct.

8 Q. The purpose of which is to re-focus efforts within the
9 program to ensure continued compliance among the registrant
10 population. Do you see that?

11 A. Yes.

12 Q. And that is why you were updating the diversion manual,
13 correct?

14 A. That and there were other things (unintelligible) --

15 COURT REPORTER: I'm sorry. Other things --

16 THE WITNESS: There were other provisions in the
17 manual that needed to be updated because of different
18 changes in law.

19 BY MR. SCHMIDT:

20 Q. And then the next paragraph says until such time as the
21 manual is finalized, the attached interim guidelines will be
22 implemented. And then you say it's the responsibility of
23 all Diversion Program Managers and Diversion Group
24 Supervisors to ensure the documented interim guidelines are
25 incorporated into current and future investigations and work

1 plans upon receipt of this memorandum. Do you see that?

2 **A.** What was the question?

3 **Q.** Do you see that language?

4 **A.** Yes.

5 **Q.** And then if you look at the attachment, you did, in
6 fact, attach the interim policy in lieu of diversion manual
7 changes, correct?

8 **A.** Yes.

9 **Q.** This was an update to the diversion manual policies on
10 your watch, correct?

11 **A.** Yes.

12 **Q.** All right. Let's look at these changes in the policies
13 on your watch. Can we go to 3, please? And do you see it
14 says suspicious order reporting? Do you see that language
15 at the bottom of -- it's that funny thing where if you look
16 in the lower left corner, I'm going to always be using those
17 numbers.

18 **A.** Okay.

19 **Q.** So, it's actually Page 2 in the document, but Page 3 in
20 the lower left corner.

21 **A.** Yeah. I've got it.

22 **Q.** And do you see where it says suspicious order
23 reporting?

24 **A.** Yes.

25 **Q.** It states OD, that's the Office of Diversion, right?

1 **A.** Yes.

2 **Q.** In conjunction with CCD, has notified in writing, all
3 distributors of their responsibility to immediately report
4 all, quote, "suspicious orders", quote. Do you see that?

5 **A.** Yes.

6 **Q.** A suspicious order is an order, which, when received by
7 a registrant and in accordance with 21 CFR 1301.74, that's
8 the regulation you were looking at, correct?

9 **A.** Yes.

10 **Q.** The registrant determines to be suspicious. Do you see
11 that?

12 **A.** Yes.

13 **Q.** And then it says the registrant -- and it's bolded and
14 underlined for emphasis -- does not fill the order but
15 reports same to their local DEA Office. Do you see that
16 emphasized language, does not fill the order?

17 **A.** Yes.

18 **Q.** It then says -- that was new to this interim version of
19 the manual, that bold underscore language, correct?

20 **A.** Does not fill?

21 **Q.** Yes.

22 **A.** It's just -- it's just an update of the previous
23 language.

24 **Q.** That language does not appear in the prior manual as
25 applied to a single order, correct?

1 **A.** I would have to go back and look.

2 MR. SCHMIDT: Why don't we -- why don't we help
3 Mr. Rannazzisi out. Could we do a side-by-side and can we
4 put P -- on the left side, could we put P-8861 on the left?
5 If it's possible to switch those so that P-8861 is on the
6 left, please.

7 And go to Page 12 on the left, please. And if we can
8 blow up that language a little bit.

9 And then on the right, can we put DEF-WV-3842, Page 3?
10 And if we could blow up that suspicious order reporting.

11 And let's highlight, if we could, on the bottom does
12 not fill the order, singular.

13 BY MR. SCHMIDT:

14 **Q.** Do you see that language?

15 **A.** Yes.

16 **Q.** That's new to the 2009 update, correct?

17 **A.** That's new to the manual.

18 **Q.** Okay. And then the manual, the 2009, goes on to say
19 Excessive Purchase Reports from registrants, reports of
20 unusual size, will no longer be accepted by the DEA,
21 correct?

22 **A.** That is correct, yes.

23 **Q.** And that bold underline language in the second
24 sentence, will no longer be accepted, it doesn't say they've
25 never been accepted. It says they will no longer be

1 accepted, correct?

2 **A.** Yes. I can give you an explanation, if you would like,
3 why it says that.

4 **Q.** And it says any firm still reporting excessive
5 purchases. So you knew firms were doing that, right?

6 **A.** Uh-huh.

7 **Q.** Will be informed of the OD directive and instructed to
8 immediately report, quote, "suspicious orders", quote. Do
9 you see that?

10 **A.** Yes. And the reason that was placed there was because
11 even after we instructed the firms in the letters and even
12 though that we had the face-to-face meetings they were still
13 sending Excessive Purchase Reports and we decided that
14 instead of continuing to receive these Excessive Purchase
15 Reports, which were not Suspicious Order Reports, and we
16 told them those are not Suspicious Order Reports, to just
17 stop sending the Excessive Purchase Reports totally.

18 Even though they knew that those weren't Excessive
19 Purchase Reports they continued to send them. The only way
20 to stop it is just to tell them to stop it. That's why that
21 provision was put in there.

22 **Q.** That language does not appear in the Diversion
23 Investigators Manual from before your tenure, correct?

24 **A.** It doesn't appear to appear, yes.

25 **Q.** And let's just show exactly what we're looking at in

1 the old version before, Mr. Rannazzisi. Can you highlight
2 the supplier can determine whether an order is excessive?
3 Starting on the sixth line, the supplier can determine
4 whether the order is excessive. Do you see that?

5 **A.** Yes.

6 **Q.** Okay. Despite referencing the possibility of an order
7 being excessive before your watch there's no language saying
8 Excessive Purchase Reports will not be accepted, correct?

9 **A.** No, but the line above it talks about what suspicious
10 orders are, which is different than excessive purchases.

11 **Q.** And then the language you have, Excessive Purchase
12 Reports will no longer be accepted, that doesn't appear in
13 the version of the manual before your time; is that right?

14 **A.** That's right.

15 **Q.** And then this language about does not fill the single
16 order does not appear in the version of the manual before
17 your watch, correct?

18 **A.** No, it does not.

19 **Q.** And what the version of the manual before your watch
20 refers to is -- let's highlight starting on the midpoint,
21 this activity, refers to this activity, suspicious orders,
22 over extended periods of time, correct?

23 **A.** That's a vague statement, over extended periods of
24 time. That could be a couple of weeks. It could be a
25 month.

1 Q. And you took that language out in your version,
2 correct?

3 A. Yes. It was -- that was the language that was removed,
4 yes.

5 Q. And both of those were changes, right, to the language?

6 A. Yes. It was because we were reemphasizing suspicious
7 orders because they weren't being followed.

8 Q. One --

9 A. The suspicious order guidelines were not being
10 followed, so we reemphasized it in the manual.

11 Q. One change in the manual is you removed any linkage
12 between determining whether an order is excessive and
13 exceeding a threshold being suspicious. You removed that
14 linkage, correct?

15 A. That's no longer in the 2010 manual, yes.

16 Q. And instead you changed it to say we don't accept these
17 policies any longer, correct; these reports, I'm sorry, any
18 longer, correct?

19 A. Yes. We said that.

20 Q. And instead of talking about suspicious orders over
21 extended periods of time leading a reasonable person to
22 believe that controlled substances possibly are being
23 diverted, you changed it to say the registrant does not fill
24 the order, singular, correct?

25 A. That's correct.

1 Q. Okay.

2 A. Which is consistent with the letters that we sent.
3 Which is consistent with *Southwood*. Which is consistent
4 with the distributor initiative briefings, which happened
5 way before 2010.

6 Q. Okay. I want to talk about just what you just
7 mentioned, *Southwood*.

8 A. Okay.

9 Q. And this is going to seem like diversion, but it's not.
10 You remember -- you're familiar with the *Masters*
11 *Pharmaceutical* case, correct?

12 A. Yes.

13 Q. And that was a case that was being adjudicated while
14 you were still at the DEA, correct?

15 A. I think the final decision came out after I was at DEA
16 but, yes, I was there during *Masters*.

17 MR. SCHMIDT: May I approach, Your Honor?

18 THE COURT: Yes, you may.

19 MR. SCHMIDT: Thank you.

20 BY MR. SCHMIDT:

21 Q. I've passed you what I've marked as DEF-WV-2578. Do
22 you see that this is a Federal Register entry from
23 September 5th, 2015?

24 A. Yes.

25 Q. And just to be fair, the Court has seen the DC Circuit

1 appeal that followed this decision. That came after your
2 watch. You were still at the DEA, though, on
3 September 15th, 2015, correct?

4 **A.** Yes, but when you talked about the *Masters* decision, I
5 was still thinking about the appellate decision.

6 **Q.** And that's why I wanted to be fair to you.

7 MR. ACKERMAN: Your Honor, I'm going to interpose
8 a scope objection to the extent this was not at all
9 mentioned or questioned in the MDL deposition.

10 MR. SCHMIDT: Your Honor, I don't think they get
11 to bring a witness and ask him questions, including
12 questions that were demonstrably outside the MDL over
13 objection, and then shut it down on that basis.

14 THE COURT: Overruled.

15 BY MR. SCHMIDT:

16 **Q.** So, just to go back to this decision and to orient the
17 Court to what we're talking to in that distinction between
18 the DC Circuit decision and this decision, if you look at
19 Page 85 of the decision, the last page, this is the decision
20 from the DEA itself, Chuck Rosenberg, the Acting
21 Administrator of the DEA, dated September 18th, 2018. Do
22 you see that?

23 **A.** Yes.

24 **Q.** That came while you were still at DEA, correct?

25 **A.** Yes.

1 Q. And then later, as the Court has seen, this decision
2 was appealed and that was after you left, the DC Circuit
3 decision?

4 A. Yes.

5 Q. Okay. So, I'll focus on this one for now.

6 MR. SCHMIDT: And I'll move it into evidence,
7 DEF-WV-2578.

8 THE COURT: Any objection?

9 MR. ACKERMAN: I will preserve our scope
10 objection, but I suspect you know I know how you will rule
11 on that.

12 THE COURT: Okay.

13 MR. ACKERMAN: Can I just ask for a standing
14 objection on scope matters?

15 THE COURT: Yes, you can.

16 MR. ACKERMAN: All right. Thank you. So that
17 will be preserved for the record.

18 THE COURT: Okay.

19 MR. SCHMIDT: And, of course, we have no objection
20 to any standing objections and would ask for the same
21 courtesy to make things go fast.

22 BY MR. SCHMIDT:

23 Q. All right. Let's look at Page --

24 MR. SCHMIDT: Sorry. Is this admitted, Your
25 Honor?

1 THE COURT: Yes. It's admitted. It's admitted.

2 BY MR. SCHMIDT:

3 Q. Could we go to Page 59 of the decision and let's cull
4 out the first several lines in the upper left-hand corner.
5 Two points on this decision.

6 First of all, do you see that in the second line here
7 there's reference to the Rannazzisi letters?

8 A. Okay.

9 Q. Do you see that reference?

10 A. Yes.

11 Q. And you understand that the DEA is referencing your
12 letters from the distributor initiative, 2006 and 2007,
13 correct?

14 A. I -- like I said, it's been a long time since I've seen
15 this and, quite frankly, I have no idea what is in there.
16 That was a long --

17 Q. Let's look at what they say just to answer that
18 question. Do you see there's a reference to a 2007 letter?
19 Do you see that?

20 A. Yes.

21 Q. And you wrote a letter on December 27th, 2007, correct?

22 A. Yes, I did.

23 Q. And that letter contained the very language on Page 2
24 that this DEA opinion quotes as appearing on Page 2,
25 correct?

1 **A.** Yes.

2 **Q.** And then they quote more and that language also is the
3 next sentence from your letter, also on Page 2, in December,
4 2007?

5 **A.** Could I see --

6 **Q.** Yes, of course. That's the end of the quote of your --
7 of your letter. Do you see them quoting another sentence
8 from your letter in December of 2007?

9 **A.** Okay, I see it.

10 **Q.** And then let's look at what they say about the letter.
11 They say contrary to the ALJ's understanding -- you
12 understand an ALJ is an administrative law judge, right?

13 **A.** Yes, I do.

14 **Q.** This simply is not language that manifests an intent to
15 bind the agency. Do you see that language?

16 **A.** Yes.

17 **Q.** Do you remember giving testimony yesterday that your
18 letters were intended to be official guidance from the DEA?

19 **A.** Yes.

20 **Q.** Do you know that the Administrator, the acting
21 Administrator of the DEA, had concluded that this simply,
22 with respect to the 2007 letter, is not language that
23 manifests an intent to bind the agency? Did you know about
24 that language in this decision before I showed it to you
25 just now?

1 **A.** No. I don't recall that language.

2 **Q.** Let's go to the next sentence. Nor is the 2006 letter
3 -- do you remember showing the Court the 2006 letter that
4 you sent to all registrants?

5 **A.** Yes.

6 **Q.** Nor is the 2006 letter fairly read as manifesting an
7 intent to bind the agency. Do you see that language?

8 **A.** Yes.

9 **Q.** And if we look further down, do you see that they
10 actually quote Page 2, your 2006 Dear Registrant letter?

11 **A.** Okay.

12 **Q.** Do you see that?

13 **A.** So, you're looking at Page --

14 **Q.** I'm looking at this paragraph on the screen where they
15 actually quote Page 2 of your 2006 Dear Registrant letter.

16 **A.** Yes.

17 **Q.** And when you testified yesterday that your letters were
18 official guidance of the DEA, did you know that while you
19 were there the Acting Administrator of the DEA said nor is
20 your 2006 letter fairly read as manifesting an intent to
21 bind the agency? Did you know that, sir?

22 **A.** No, I didn't. This was, again, the end of my tenure.
23 It was September when the order was released.

24 **Q.** All right. Let's look further up this page. I'm going
25 to ask you about one other point.

1 A review of the letters shows that they were not
2 intended -- and we're talking about the Rannazzisi letters
3 here. Do you see that? A review of the letters shows that
4 they were not intended to have binding effect, but were
5 simply warning letters. Did you know about that language
6 before I showed it to you just now?

7 **A.** No, but those letters didn't occur under this -- that
8 Acting Administrator. They occurred under Karen Tandy and
9 Michelle Leonhart, who were Senate confirmed Administrators,
10 not a -- an Acting Administrator.

11 **Q.** Go back to Page 85, please, and there you see this
12 title that you just pointed out, Acting Administrator; do
13 you see that?

14 **A.** Yes. Acting administrator. Not Senate confirmed.
15 Acting Administrator.

16 **Q.** Was he in charge of the DEA at this time?

17 **A.** Yes.

18 **Q.** Was he your boss at this time?

19 **A.** Yes, he was.

20 **Q.** And I take it if you didn't know about this language
21 you never took a public position while you were at the DEA
22 disagreeing with this language?

23 **A.** Well, again, in September, I was on my way out. They
24 had already replaced me at that point in time. So, no. But
25 during my tenure, when I was in charge, those letters were

1 guidance. The Administrators, the two Administrators, knew
2 about those letters and had no problem with those -- with
3 those letters issued as guidance.

4 MR. SCHMIDT: And I'll move to strike his
5 testimony about the thoughts of other -- other people.

6 THE WITNESS: Well, they were based on -- I'm
7 sorry.

8 MR. ACKERMAN: We oppose that, Your Honor.

9 THE COURT: Well, I'll sustain that one.

10 MR. ACKERMAN: I'm sorry.

11 THE COURT: I'll grant the motion to strike that
12 portion of his testimony.

13 BY MR. SCHMIDT:

14 Q. Now, I mentioned *Southwood*. Do you remember that?

15 A. Yes.

16 Q. *Southwood* talked about the due diligence requirement,
17 right?

18 A. Yes.

19 Q. And that the idea of the due diligence requirement is
20 -- it requires a registrant to first determine whether an
21 order is suspicious and, if so, take appropriate action to
22 dispel the suspicion before fulfilling the order, correct?

23 A. Yes.

24 Q. And that's this do not ship idea, right?

25 A. That's the do not ship.

1 Q. Okay. Let's look at what this opinion from the Head of
2 the DEA says about *Southwood*. Could we go to Page 60? And
3 *Southwood*, to orient us, was in 2007, correct?

4 A. The *Southwood* opinion was in 2007.

5 Q. Okay. Let's look at what they say in the upper right
6 corner, the first paragraph there. And we see there's some
7 case law citation here. I'm going to go to the sentence
8 right after that begins with "moreover" and tell me when
9 you're there. Do you see where I'm referencing?

10 A. Yes.

11 Q. Okay. It says because the due diligence rule we've
12 been discussing was announced in an adjudication, and then
13 it goes on to say respondent was free to argue why the rule
14 should not be applied in this matter as it was here in this
15 matter. Do you see that?

16 A. Yes.

17 Q. And Mr. Reynolds has helpfully underlined this rule
18 about due diligence being announced in an adjudication. Do
19 you see that?

20 A. Yes.

21 Q. And you understand, as we see in the next sentence,
22 that the adjudication in this opinion is saying that the due
23 diligence decision was announced in the *Southwood* decision,
24 correct?

25 A. I'm sorry. Please repeat that. I'm trying to look at

1 this and listen at the same time.

2 Q. Sure, no problem. When it says the due diligence rule
3 was announced in an adjudication, do you see that?

4 A. Yes.

5 Q. That reference to an adjudication?

6 A. Yes.

7 Q. You understand that the adjudication being referenced
8 is a *Southwood* decision from 2007, correct?

9 A. Yes.

10 Q. According to this, that's where this due diligence rule
11 was announced, correct?

12 A. Well, it was announced in a final order, yes, at that
13 point in time.

14 Q. And, in fact, you pointed distributors to the *Southwood*
15 decision to provide them with more information about your
16 understanding and your interpretation of the Controlled
17 Substances Act in your second letter in 2007, correct?

18 A. That's correct, December of 2007.

19 Q. All right. Let's look at one more exhibit in this
20 regard.

21 MR. SCHMIDT: May I approach, Your Honor?

22 THE COURT: Yes.

23 BY MR. SCHMIDT:

24 Q. This is a decision -- I'm sorry. This is the wrong
25 one. Can I grab that back? This is the DC Circuit *Masters*

1 decision. I didn't mean to hand you that. I'm happy to
2 talk about it, but it's after your time, so I didn't mean to
3 give you that.

4 May I approach again, your Honor?

5 THE COURT: Yes.

6 MR. SCHMIDT: So, Your Honor, what I've passed the
7 witness is an exhibit marked DEF-WV-2261. We used this with
8 Mr. Rafalski and, at the time, I think what I proposed to
9 the Court is that the Court could take judicial notice of
10 it, but it didn't make sense to move it in as an exhibit
11 yesterday, we took the decision, as an exhibit. So, I will
12 go ahead and move this into evidence.

13 THE COURT: Any objection, Mr. Ackerman?

14 MR. ACKERMAN: Yes. I think the decision that was
15 taken as an exhibit was an ALJ decision and, therefore, was
16 a public record and taken as evidences of notice. I don't
17 think we would agree that a court decision is appropriate as
18 evidence.

19 THE COURT: Well, what about it, Mr. Schmidt?

20 MR. SCHMIDT: I think it's a government record.
21 It is a literal definition of a governmental record and I
22 think there's --

23 THE COURT: Well, I can take judicial notice.

24 MR. SCHMIDT: And you can take judicial notice.

25 THE COURT: It's admitted, Mr. Ackerman.

1 MR. ACKERMAN: Your Honor, can I clarify something
2 for the record because --

3 THE COURT: Mr. Schmidt, let's --

4 MR. SCHMIDT: Sorry.

5 MR. ACKERMAN: I think he was just asking Mr.
6 Rannazzisi if he needed water.

7 I just wanted to clarify something for the record
8 because this is an issue that has come up several times. I
9 think it came up with direct sales. I think it came up
10 other times in this litigation. If the Court is going to be
11 accepting -- there were instances where the Court did not
12 accept judicial decisions as evidence or exhibits in this
13 case.

14 And so, if that -- if the Court is going to adopt a
15 different practice at this time, that's perfectly within the
16 Court's discretion. I just want to make it clear because I
17 know this is an issue likely in deposition designation
18 exhibits to objections and elsewhere.

19 THE COURT: Well, I'm not sure I understand why
20 there's an issue about this.

21 MR. ACKERMAN: So, the decision that we moved in
22 yesterday was *Southwood Pharmaceuticals*, which was from the
23 DEA website, and it was in the Federal Register like this
24 *Masters* decision. I understand.

25 These are court decisions. They're not -- they can't

1 be admitted for the truth. I -- I'm certainly not going to
2 question that a judge is not reliable, but we have heard
3 from defendants over and over again in this trial that
4 judicial opinions aren't evidence.

5 So, I don't understand the purpose for which they're
6 being offered and I believe the Court has rejected earlier
7 attempts to put judicial opinions in as evidence.

8 MR. SCHMIDT: And Mr. Ackerman is right. We have
9 objected. We've taken the position that they're notice with
10 change. And the reason I move this in now and not before is
11 yesterday the Court admitted the *Southwood* decision. Our
12 view is that's exactly the same principle subject to
13 judicial notice.

14 Frankly, I don't think we have a strong view either
15 way, but if some key opinions are going in the record, we
16 think this is a key opinion that should go in the record. I
17 think it's a little bit of an academic dispute and, on my
18 part, is prompted only by *Southwood* going in yesterday and
19 I'm wanting to make sure that the Court has access readily
20 in an easy form in the record to what we're talking about.

21 But I do think the point is right. The Court can take
22 notice. So, whichever the easiest way to deal with it is,
23 I'm fine with proceeding. It's something that's before the
24 Court. I think the Court has taken judicial notice of this
25 decision. I don't think any of these materials need to be

1 in the record in terms of the *Southwood* decision yesterday,
2 but if we are admitting them, it makes sense to treat them
3 the same.

4 THE COURT: Well, what -- what is the purpose that
5 it's admitted? It's not coming in for the -- just tell me
6 what the -- what the purpose of it as evidence is.

7 MR. SCHMIDT: The purpose of it as evidence is it
8 documents sworn testimony in the case from Mr. Rannazzisi's
9 colleagues on his watch while he was at DEA on relevant
10 points in this litigation.

11 THE COURT: Well, you could use it as a basis to
12 ask him about that without admitting it, couldn't you?

13 MR. SCHMIDT: Yes, but I think if we're going to
14 admit some decisions like *Southwood* from yesterday, the
15 better course is to admit this.

16 THE COURT: Mr. Ackerman?

17 MR. ACKERMAN: The distinction, Your Honor, that
18 we have made is that we admitted *Southwood* as notice to the
19 defendants. This is not being offered for notice. It's
20 being offered essentially for the truth of the matter
21 asserted therein.

22 MR. SCHMIDT: *Southwood* was not admitted under a
23 limited basis.

24 MR. ACKERMAN: And it was a public record of the
25 DEA, not of a -- this is --

1 MR. SCHMIDT: A public record of the United States
2 Judiciary, Article III of the Constitution.

3 MR. ACKERMAN: I'm going back to my rules, Your
4 Honor. 803(8) says a record or statement of public office,
5 and I don't know whether the Judiciary in and of itself is a
6 public office. I am just going to say that's what the rule
7 says.

8 THE COURT: I don't understand why there's a big
9 argument about this when it's a matter that -- a public
10 record that the Court could take judicial notice of. Why
11 does it have to be admitted as evidence or not as admitted
12 as evidence?

13 MR. SCHMIDT: That's what I was going to say.
14 With that statement from the Court, I'll just question on it
15 and I'll -- I'll move on.

16 BY MR. SCHMIDT:

17 **Q.** You have in front of you DEF-WV-2261.

18 **A.** Yes.

19 **Q.** And do you understand that this is a decision involving
20 the United States while you were at DEA from the Eastern
21 District of Michigan in 2012?

22 **A.** Yes.

23 **Q.** And do you have the understanding from seeing this
24 decision before, and I can point you to a specific portion
25 of the opinion, that it reflects testimony from people in

1 your office, Kyle Wright, Michael Mapes, James Rafalski,
2 under your supervision as Head of the Office of Diversion
3 Control?

4 **A.** I seem to remember Kyle Wright. I didn't know Mike
5 Mapes was involved in this.

6 **Q.** Okay. And let me actually correct. I'm not sure if he
7 gave testimony, but he's quoted in the opinion. So, let's
8 look at Page 6 of the opinion, please. If we could cull out
9 the third paragraph, please.

10 It says the government offered testimony that the DEA
11 sought to expand drug wholesalers' obligations by a policy
12 change in 2006 and 2007, although there was never a change
13 to the regulations.

14 THE COURT: Mr. Ackerman?

15 MR. ACKERMAN: Objection, Your Honor, and this is
16 the problem that we get into. This is several levels of
17 hearsay because this is now the Court saying that the
18 government said something. We don't have any access to the
19 record in this case. If there was testimony by the
20 government, it's something that we can assess, but at this
21 point, we're now cross examining based on the two or three
22 levels of hearsay.

23 THE COURT: He's offering this as evidence. If I
24 understand what's going on here, he's offering -- he's using
25 it as a good faith basis to cross-examine the witness and

1 it's perfectly proper for that purpose.

2 MR. SCHMIDT: And just for the record, you do have
3 the testimony from this case. We've used it in depositions
4 with Mr. Rafalski.

5 THE COURT: Overruled. You can go ahead, Mr.
6 Schmidt.

7 BY MR. SCHMIDT:

8 Q. Do you see this language about testimony from
9 government officials that the DEA sought to expand drug
10 wholesalers' obligations by a policy change in 2006 and
11 2007, although there was never a change to the regulations?
12 Do you see that?

13 A. I see that, yes.

14 Q. And the point about there was never a change to the
15 regulations, that's true, right?

16 A. There was not a change to the regulations, no.

17 Q. And whatever testimony was offered in this case from
18 DEA officials came from DEA officials you supervised,
19 correct?

20 A. Well, if it's Kyle Wright, yes. He was under my
21 supervision.

22 Q. And, in fact, just so we're clear, at one point, you
23 were going to give testimony in this case, correct, but
24 because of a kind of timing issue as to when your disclosure
25 was made, you weren't able to give testimony, correct?

1 **A.** That's correct.

2 **Q.** Okay. One of the changes -- I think you were going to
3 give expert testimony, correct?

4 **A.** I was going to give testimony on the suspicious order
5 monitoring requirements.

6 **Q.** Okay. One of the changes in interpretation by the DEA
7 concerned the circumstances under which a distributor should
8 suspend shipments to a customer if it identified the
9 customer -- if it identified an order as suspicious. Do you
10 see that?

11 **A.** Yes.

12 **Q.** And that's the do not ship policy you understand being
13 referenced there?

14 **A.** Yes.

15 **Q.** That change in policy apparently prompted concern
16 within the DEA compliance sectors that confusion would
17 result since the prior report-only policy had been in place
18 for 35 years and then it refers to DEA personnel began to
19 conduct distributor briefings to familiarize drug
20 wholesalers with the new policy. Do you see that?

21 **A.** Yes.

22 **Q.** And you understand from the time period that those
23 distributor briefings are the same ones we've been talking
24 about throughout your testimony, correct?

25 **A.** Yes.

1 **Q.** Goes on to say Kyle Wright, who you supervised, it says
2 DEA began to conduct distributor briefings to -- I'm sorry.
3 Kyle Wright, the Unit Chief of the E-commerce section at the
4 Office of Diversion Control at the DEA Headquarters in
5 Washington, D.C. in 2006 and 2007, testified that he played
6 an important role in developing the briefings. Do you see
7 that?

8 **A.** Yes.

9 **Q.** Is that true?

10 **A.** Yes.

11 **Q.** Let's go to the next paragraph. In all events, Wright
12 testified that the DEA was aware that it was standard
13 practice in the industry to file Suspicious Order Reports
14 while continuing to ship products, and that practice had
15 been approved by the DEA. Do you see that?

16 **A.** Yes.

17 **Q.** Do you recall me asking you yesterday about the fact
18 that there was a window, I think, between 19 -- I'm going to
19 get the years wrong, is it '88 and 2005, where you didn't
20 deal with distributors? Do you remember that?

21 **A.** Yes.

22 **Q.** Mr. Wright was dealing with distributors before 2005,
23 correct?

24 **A.** Yes.

25 **Q.** And then here's where I might have gotten tripped up.

1 Let's go to the next paragraph, please. In the second
2 sentence, it says Wright's supervisor, Michael Mapes, told
3 distributors at the DEA's Pharmaceutical Industry Conference
4 on September 11th, 2007 that the DEA's new interpretation of
5 the suspicious order regulation was that distributors should
6 suspend shipments if they routinely report suspicious orders
7 with reason to believe they are destined for the illicit
8 market. Do you see that?

9 **A.** I see that.

10 **Q.** Did you attend that conference with Mr. Mapes?

11 **A.** No, I did not.

12 **Q.** Did you issue any public statements disagreeing with
13 this decision when it came out in 2012 on your watch?

14 **A.** No, I did not.

15 **Q.** I want to go back to reports that were made before 2008
16 and you talked about that term "Excessive Purchase Reports";
17 do you recall that?

18 **A.** Yes.

19 **Q.** Do you know that McKesson believed it was making
20 Suspicious Order Reports before that period?

21 **A.** Yes.

22 **Q.** And let's look at what we're -- let's show the judge
23 what we're talking about.

24 **A.** Suspicious or excessive?

25 **Q.** Suspicious.

1 **A.** I don't know if -- what McKesson believed or what they
2 didn't believe, to be honest with you.

3 **Q.** Okay, fair enough. They told the DEA they were making
4 suspicious reports, correct?

5 **A.** I'm not aware of them telling the DEA that they made
6 suspicious reports.

7 **Q.** Okay. Do you have that massive set of reports --

8 **A.** Yes.

9 **Q.** -- 42747 in front of you?

10 **A.** Yes.

11 **Q.** And if we go to the second page of that document, and
12 if we look at the heading where it says "McKesson
13 Corporation".

14 **A.** Okay.

15 **Q.** Do you see right under there it says Monthly Controlled
16 Substance Order Report? Do you see that?

17 **A.** Yes.

18 **Q.** Okay. And then let's look down at this language here
19 and this is what I want to focus on. Pursuant to CFR 21
20 Section 1301.74(B). Do you see that?

21 **A.** Yes.

22 **Q.** Is that the regulation we were looking at that is the
23 suspicious order regulation?

24 **A.** Yes.

25 **Q.** So, they say pursuant to the suspicious order

1 regulation we are sending a copy of the Monthly Controlled
2 Substance Order Report for September, '09. Do you see that?

3 **A.** Yes.

4 **Q.** And then do you remember saying that they never
5 explained why --

6 **A.** Yes.

7 **Q.** -- they were flagging the orders?

8 **A.** Uh-huh.

9 **Q.** Let's look at the explanation. It says this report
10 reflects purchases from customers for Schedules II-V,
11 controlled substances which exceed the item monthly average
12 for the class of trade. Do you see that?

13 **A.** Yes.

14 **Q.** And remember the Diversion Investigators Manual we've
15 looked at that talked about exceeding thresholds?

16 **A.** Yes.

17 **Q.** This is telling DEA that the way these are identified
18 is they exceed the item monthly average for the class of
19 trade, correct?

20 **A.** That's what it says, but that's still not a suspicious
21 order.

22 **Q.** If we go on, it says a listing of the parameters used
23 are available upon request. Do you see that?

24 **A.** Yes.

25 **Q.** Were they ever requested, to your knowledge? Do you

1 know?

2 **A.** I don't know. But, again, this is not a suspicious
3 order. First of all, this is monthly. It's supposed to be
4 done when discovered. And you're supposed to have a
5 description of why it's suspicious, not just that it
6 breached threshold.

7 You're supposed to talk about the pharmacy. Explain
8 why this pharmacy is doing something suspicious. Not just
9 -- not just, oh, they were above threshold. That means
10 nothing to us.

11 **Q.** Let's go back to DEF-WV-640. Do you remember this
12 language in the regulation?

13 **A.** Yes.

14 **Q.** Where does it say in there you've got to tell us about
15 the pharmacy or why you say it's suspicious?

16 **A.** It doesn't. It says it in the letters that we wrote
17 providing guidance.

18 **Q.** Is there a letter you wrote that says you need to tell
19 us information about this pharmacy?

20 **A.** It says that you have to explain why an order is
21 suspicious. Just being over threshold is not suspicious.

22 **Q.** When did you write that letter?

23 **A.** I think 2006 and -- one of the 2006 or 2007 letters,
24 one of those letters has it. It was also described in the
25 distributor briefings.

1 Q. Which you didn't attend?

2 A. That I didn't attend, that's exactly right.

3 Q. I'll come back to that. Let's go back to the report.

4 A. Okay.

5 Q. Sorry. 42747, Page 2, please, back to the report that
6 you looked at for counsel for the plaintiffs.

7 A. Yes.

8 Q. And I want to focus again on this language, a listing
9 of parameters used are available upon request. Do you see
10 that?

11 A. Yes.

12 Q. Do you know how many times during audits,
13 registrations, otherwise, DEA officials looked at the
14 parameters that were used to determine whether this report
15 that McKesson was making pursuant to the suspicious order
16 regulation, how those worked? Do you know how many times
17 DEA agents looked at those?

18 A. No, sir, I don't.

19 Q. All right. Let's go back to DEF-WV-1549. Just to be
20 clear, could we go back to 42747? And I just want to be
21 absolutely clear for the record on this in case I didn't get
22 it.

23 If we could highlight that language pursuant to 21 C.
24 F. R. 1301.74(B).

25 Do you see that language?

1 **A.** Yes.

2 **Q.** Let's go back to DEF-WV-640. This is the suspicious
3 order regulation, 1301.74(B), that we've been talking about
4 that McKesson told the DEA was the basis for it making those
5 reports, correct?

6 **A.** Yes.

7 **Q.** Okay. So, let's look at the letter that we talked
8 about a little bit yesterday. I want to finish up with this
9 letter from January 23rd, 2006, the DEA memo to you from Mr.
10 Mapes, dated -- Bates stamped -- exhibit stamped
11 DEF-WV-1549. Do you remember talking about this letter?

12 **A.** Yes. I'm trying to find it.

13 **Q.** And if we go to the second page, I want to just blow up
14 the pharmacies being discussed here.

15 **A.** Yes.

16 **Q.** And you recall we talked a little bit about these six
17 pharmacies that the DEA identified based on ARCOS data,
18 correct?

19 **A.** That's correct.

20 **Q.** And they were identifying generic and branded
21 hydrocodone sales, correct?

22 **A.** I'm sorry. Who was --

23 **Q.** The DEA. These numbers included generic and branded
24 hydrocodone numbers, correct?

25 **A.** Yes.

1 Q. And that came from the ARCOS data that McKesson
2 reported to the DEA, correct?

3 A. Yes.

4 Q. McKesson was reporting both generic data and branded
5 data, correct?

6 A. Yes.

7 MR. SCHMIDT: May I approach, Your Honor?

8 THE COURT: Yes.

9 BY MR. SCHMIDT:

10 Q. I've passed you something marked MC-WV-2143 and let's
11 go to the second page. Do you see that this is the type of
12 DU45 report that you said you had seen at the DEA?

13 A. I believe I saw this report at one point in time, yes.

14 Q. Okay. Let's look at what it says.

15 MR. SCHMIDT: I'll move it into evidence on that
16 basis, Your Honor.

17 THE COURT: Any objection?

18 MR. ACKERMAN: No objection.

19 THE COURT: It's admitted.

20 BY MR. SCHMIDT:

21 Q. If we look at the top, do you see where it says Daily
22 Controlled Substance Suspicious Purchase Report? Do you see
23 it refers to a daily report?

24 A. Yes.

25 Q. And if we look in the upper left-hand corner, it gives

1 us the date -- sorry. It gives us the date that this
2 particular report was run, November 25th. Do you see that?

3 **A.** Yes. And then if we look down, it has reports from
4 earlier dates included.

5 MR. SCHMIDT: Can you take that down?

6 BY MR. SCHMIDT:

7 **Q.** Going all the way back to November 7th. Do you see
8 that?

9 **A.** Yes.

10 **Q.** And if you look at that language we looked at in the
11 other document right here, do you see that it again
12 references the suspicious order regulation of 21 CFR
13 1301.74(B)?

14 **A.** Yes.

15 **Q.** Do you see it says we are sending a copy of the Daily
16 Controlled Substance Suspicious Purchase Report for
17 November 25th, 2005?

18 **A.** Yes.

19 **Q.** And that it again says we picked it based on exceeding
20 the item monthly average listing the parameters used are
21 available upon request. Do you see that?

22 **A.** Yes.

23 **Q.** All right. Let's see if we can put on the left-hand
24 side of the screen DEF-WV-1549 and on the right-hand side of
25 the screen the document we currently have up.

1 And what I would like to do on the left side is on Page
2 2. So, just to orient us, on the left side, we have the
3 memo you received in January of 2006 reflecting the
4 discussion with McKesson, correct?

5 **A.** Say that again.

6 **Q.** On the left-hand side we have the memo you received in
7 January, 2006 reflecting the discussion with McKesson?

8 **A.** Yes.

9 **Q.** And it lists the six pharmacies that were raised with
10 McKesson at that January meeting?

11 **A.** Yes.

12 **Q.** Let's look at the first one of those pharmacies.

13 MR. SCHMIDT: Could you highlight on the left
14 AccuMed just down at the bottom?

15 BY MR. SCHMIDT:

16 **Q.** Do you see AccuMed at the bottom of the memo as one of
17 the six pharmacies that was discussed?

18 **A.** Yes.

19 **Q.** And do you see on the right, if we go to Page -- I'm
20 sorry. I think I skipped us ahead.

21 MR. SCHMIDT: Just to make it easier, could you
22 highlight MediPharm?

23 BY MR. SCHMIDT:

24 **Q.** Do you see MediPharm is one of the pharmacies that was
25 discussed in the January meeting with McKesson?

1 **A.** Yes.

2 **Q.** If we look on the right, do you see that this is,
3 according to the document at least, a Daily Controlled
4 Substance Suspicious Purchase Report for MediPharm from
5 November of 2005? Do you see that?

6 **A.** Yes.

7 **Q.** Okay. And if we look down on the form --

8 MR. SCHMIDT: Can we go to Page 8, please? On the
9 right. I'm sorry. Let's go to the next one.

10 BY MR. SCHMIDT:

11 **Q.** Do you see that Page 8 is AccuMed? Do you see that?

12 **A.** Yes.

13 **Q.** And do you see that AccuMed is another one of the
14 pharmacies listed in your letter?

15 **A.** Yes.

16 **Q.** And if we take down that AccuMed cull-out, do you see
17 that under the AccuMed listing there are listings for a
18 product called Norco, which is a branded prescription
19 opioid? Do you see that? It's a little bit hard to read,
20 but do you see that reference to the branded products?

21 **A.** Yes.

22 **Q.** And then there's a reference below to generic
23 hydrocodone, correct?

24 **A.** Yes.

25 **Q.** And these reports that McKesson was making pursuant to

1 the suspicious order regulation included branded products
2 and generic products, correct?

3 **A.** Yes.

4 **Q.** All right. And just -- we'll do this as quickly as
5 possible.

6 MR. SCHMIDT: Could we put up -- we've done
7 MediPharm. We've done AccuMed. Could we put up Page 5 on
8 the right?

9 BY MR. SCHMIDT:

10 **Q.** Do you see that this is Bi-Wise report on Page 5?

11 **A.** Yes.

12 **Q.** And do you see Bi-Wise is another one of the six
13 pharmacies on Page -- on your January memo?

14 **A.** Yes.

15 MR. SCHMIDT: Let's put up Page 21 on the right.

16 BY MR. SCHMIDT:

17 **Q.** Do you see that this is of Avee Pharmacy with reports
18 made pursuant to the suspicious order regulation on the
19 right, Page 21?

20 **A.** Okay.

21 **Q.** And Avee is another pharmacy mentioned in your memo in
22 January, two months later, correct?

23 **A.** Yes.

24 **Q.** Let's go to Page 25. Do you see that there's Universal
25 Rx on the right with reports pursuant to the suspicious

1 order regulation?

2 **A.** Yes.

3 **Q.** And do you see that on the left that's another one of
4 the pharmacies mentioned? Do you see that?

5 **A.** Yes.

6 **Q.** And last one, Page 48 on the right, United Prescription
7 Services, also reports from November, 2005. Do you see
8 that?

9 **A.** Yes.

10 **Q.** And they're also one of the pharmacies discussed on the
11 left. Do you see that?

12 **A.** Yes.

13 **Q.** And so we know from looking at this that McKesson's
14 data as it provided it to the DEA -- and ARCOS identified
15 generic and branded data, correct?

16 **A.** Yes. It looks that way, yes.

17 **Q.** And in these reports made pursuant to the suspicious
18 order regulation, they've identified generic and branded
19 data, correct?

20 **A.** Well, these reports aren't made pursuant to suspicious
21 order. They weren't reported as discovered. Some of these
22 reports -- if you go by the fax sheet here, some of these
23 reports were three, four days after the fax sheet. Some of
24 these reports happened -- the fax sheet is dated 1/28. Some
25 of these reports are -- or 11/28. Some of these reports are

1 after 11/29. So, if the fax sheet is dated 11/28, how could
2 they possibly be reported the day after the fax was actually
3 faxed?

4 **Q.** If you flip through that document, do you see there are
5 multiple fax sheets in there?

6 **A.** No. I didn't see multiple fax sheets. Okay. I found
7 one. But still --

8 **Q.** Let me address your other point, if I could, Mr.
9 Rannazzisi.

10 **A.** Yeah.

11 **Q.** Did you know these were rolling reports, so that when
12 they made the daily report, they provide the previous
13 reports made for that pharmacy in a month? Do you know
14 whether that was the case or not?

15 **A.** No. I don't know whether that was the case.

16 **Q.** Let me go back to my question and let's cull out this
17 language pursuant to CFR Section 1301.74(B), right?

18 **A.** Yeah.

19 **Q.** McKesson said it was providing DEA with reports
20 pursuant to the suspicious order regulation that covered
21 both generic and branded opioids, correct?

22 **A.** It looks that way, yes, in these reports, yes.

23 **Q.** Now, I touched yesterday on changes McKesson made to
24 its suspicious order monitoring policy in response to some
25 of these discussions in 2005 and 2006 with the DEA about

1 these pharmacies in Florida. Do you remember touching on
2 that briefly yesterday afternoon?

3 **A.** Could you repeat the question, please?

4 **Q.** Sure. And why don't I just go to the meat of it. Are
5 you aware that following discussions with the DEA in 2005
6 and 2006, McKesson twice updated its policies regarding
7 suspicious order monitoring?

8 **A.** Yes. I was told that they did their suspicious order
9 monitoring, yes.

10 **Q.** Let's go ahead. I'm going to pass out Exhibit
11 DEF-WV-1527.

12 MR. SCHMIDT: May I approach with that, Your
13 Honor?

14 BY MR. SCHMIDT:

15 **Q.** And this is a letter on the cover written for -- from
16 counsel for McKesson, June 12th, 2007, to Linden Barber,
17 Office of Chief Counsel at the Drug Enforcement
18 Administration. You know Mr. Barber, correct?

19 **A.** Yes, I do.

20 **Q.** He was a former colleague of yours at the DEA, correct?

21 **A.** Yes.

22 **Q.** And if we look down, he says I have attached a copy of
23 the following information: Amendment to the McKesson DC
24 Operations Manual describing the standard operating
25 procedures for the lifestyle Drug Monitoring Program and

1 then a PowerPoint presentation on that program. Do you see
2 that?

3 **A.** Yes.

4 **Q.** Is that one of the policies that you were told, one of
5 the policy changes McKesson made following these discussions
6 about these pharmacies in this 2005, 2006, 2007 time period?

7 **A.** I can't tell you exactly, but I was told that they
8 changed their -- their Suspicious Order Monitoring Program
9 policies, but I -- I can't remember what I was told.

10 **Q.** Okay. So, if we go --

11 MR. SCHMIDT: I'll move this into -- into
12 evidence. It's on the stipulation.

13 THE COURT: Any objection?

14 MR. ACKERMAN: No objection, Your Honor.

15 THE COURT: All right. It's admitted.

16 MR. SCHMIDT: May I confer for just one moment?

17 (Pause)

18 BY MR. SCHMIDT:

19 **Q.** Do you see that if we go to Page 3 of this document
20 there actually is a copy of the Lifestyle Drug Monitoring
21 Program being referenced? Do you see that?

22 **A.** Yes.

23 **Q.** And then if you go to Page 10 of the document, there's
24 a copy of those PowerPoint slides from Mr. Walker, Senior
25 Vice President Distribution Operations that's referenced?

1 **A.** Yes.

2 **Q.** Did you ever review those materials when you were at
3 DEA?

4 **A.** No.

5 **Q.** Are you aware of anyone raising concerns about this
6 policy when it was sent to your colleagues at DEA?

7 **A.** I -- I'm sure they would have had -- they would have
8 had concerns about it, but it wasn't brought to my
9 attention.

10 **Q.** Are there any you can point me to that you know about
11 factually?

12 **A.** That was told to me? No.

13 MR. SCHMIDT: And then one more document in this
14 area and then this may be a good time for a break, Your
15 Honor.

16 May I approach again?

17 THE COURT: Yes.

18 BY MR. SCHMIDT:

19 **Q.** Are you aware that in 2008 McKesson adopted a policy
20 called the Controlled Substance Monitoring Program?

21 **A.** Yes.

22 **Q.** And this document is in evidence, McKesson West
23 Virginia 397. Are you aware that Don Walker, the person we
24 just spoke about from McKesson, came in and gave a
25 presentation on the Controlled Substance Monitoring Program

1 and provided a copy of that policy to your colleagues at the
2 DEA?

3 **A.** No, I'm not aware of that.

4 **Q.** Okay.

5 **A.** I mean, I'm sure I was told about it, but I can't give
6 you any information about that meeting.

7 **Q.** There's no objections you can tell me or concerns that
8 anyone at DEA raised in response to the presentation or the
9 policy, correct?

10 MR. ACKERMAN: To his knowledge, right?

11 BY MR. SCHMIDT:

12 **Q.** To your knowledge, of course?

13 **A.** To my knowledge, no.

14 MR. SCHMIDT: And then I can stop here or I can do
15 two more minutes, Your Honor. Up to the Court. Probably
16 like five more minutes.

17 THE COURT: I think this a good place to stop, Mr.
18 Schmidt. We'll be in recess for 10 to 15 minutes.

19 (Recess taken)

20 (Proceedings resumed at 10:30 a.m. as follows:)

21 MR. SCHMIDT: May I proceed, Your Honor?

22 BY MR. SCHMIDT:

23 **Q.** Mr. Rannazzisi, are you good to proceed?

24 **A.** Yes, sir.

25 **Q.** Thank you, sir. I'd like to continue with one more

1 point on McKesson.

2 Let's take a look at the 2008 Settlement Agreement that
3 you talked about with counsel, P-23736. Tell me when you're
4 ready to testify about that.

5 **A.** You can go ahead.

6 **Q.** Do you recall being asked yesterday about this
7 agreement covering Lakeland, Landover, Conroe, and Denver in
8 terms of those distribution centers?

9 **A.** Yes.

10 **Q.** Are you aware that none of those distribution centers
11 regularly service Huntington and Cabell County?

12 **A.** I -- that I don't know.

13 **Q.** Okay. Fair enough. Do you know that the Washington
14 Court House distribution center does regularly service
15 Huntington and Cabell County?

16 **A.** Again, if you're asking me back then, I did not know.

17 **Q.** Okay. You understand that Washington Court House isn't
18 mentioned in this agreement?

19 **A.** I don't believe Washington Court House is mentioned.

20 **Q.** You talked about yesterday about how many distribution
21 centers the distributors have. How many does McKesson have?

22 **A.** I believe from yesterday 27, 26.

23 **Q.** Okay. Let's take 26. Four out of 26 -- when you gave
24 testimony yesterday about this, whether this was or was not
25 a systemic issue, the distribution centers covered by this

1 agreement are less than 20 percent of the 26 distribution
2 centers you just referenced; correct?

3 **A.** We don't look at it that way.

4 **Q.** Okay.

5 **A.** The way --

6 **Q.** Am I right or am I not?

7 **A.** 20 percent, but that's a lot of diversion occurring.
8 20 percent -- these are big facilities that treat a lot of
9 pharmacies, distributes to a lot of pharmacies.

10 **Q.** Okay. Let's go to the second page. Just so we have
11 it, you understand that this agreement contains no admission
12 or concession; correct?

13 **A.** Yes.

14 **Q.** Let's go to -- well, actually, before I go on in this,
15 there was no immediate -- I believe you testified to this.
16 There was no Immediate Suspension Order issued by the DEA
17 leading up to this Settlement Agreement; correct?

18 **A.** I'd have to go back and look, but I don't recall -- I
19 don't recall an Immediate Suspension Order. There may have
20 been. I just don't recall.

21 **Q.** Okay.

22 **A.** I know there was Orders to Show Cause. There were at
23 least four orders -- or three Orders to Show Cause.

24 **Q.** And we saw those and we see those referenced in the
25 agreement; correct?

1 **A.** Yes.

2 **Q.** And there's no reference and no recollection you have
3 of an Immediate Suspension Order; correct?

4 **A.** No, not that I -- I don't recall an Immediate
5 Suspension Order. I just recall the Orders to Show Cause.

6 **Q.** And DEA would issue an Immediate Suspension Order when
7 you were at DEA if there was an imminent danger to the
8 public health or safety; correct?

9 **A.** That's correct.

10 **Q.** Let's turn to Page 4. And this is in the section that
11 talks about obligations of McKesson. And this is language I
12 think you were shown yesterday.

13 If we go to (e), "McKesson agrees that any express or
14 implied approval by DEA of any previously implemented system
15 to detect and report suspicious orders is hereby rescinded
16 and is of no legal effect."

17 Do you see that language?

18 **A.** Yes.

19 **Q.** Am I correct that you saw a need to write into this
20 agreement that any prior approvals, express or implied, by
21 DEA were rescinded?

22 **A.** Yes. We put that in there because, again, the industry
23 as a whole felt there were approved systems and we wanted to
24 make sure that was correct.

25 **Q.** And we talked about how you came into Diversion Control

1 in 2005; correct?

2 **A.** That's correct.

3 **Q.** Just "yes" or "no" have you seen documents that led
4 defendants, including McKesson, to believe that their
5 systems had been approved prior to that time?

6 **A.** No, I don't believe I have seen a document.

7 **Q.** Okay. Let's go on to Page 6, please. And you were
8 shown -- well, let's start with (e). Do you see that it
9 says, "Within 150 days of the effective date of this
10 agreement, but not earlier than 90 days after the effective
11 date of this agreement, DEA shall conduct reviews of the
12 functionality of McKesson's diversion compliance program at
13 up to eight distribution centers of McKesson."

14 Do you see that language?

15 **A.** Yes.

16 **Q.** And you understand that when this is talking about
17 conducting reviews of the functionality of McKesson's
18 diversion compliance program, it's talking about that CSMP
19 that we referred to before the break?

20 **A.** Whatever system was in place at that time.

21 **Q.** And do you take issue with the CSM -- with the
22 testimony the Court has heard about the CSMP being in place
23 at that time?

24 **A.** No, I don't take issue with it. I'm just saying
25 whatever system we had in place at that time.

1 **Q.** Got it. And you would -- if we look at this section,
2 this section appears in a portion of the report if you want
3 to look back at Page 5.

4 Let's put it up on the screen for just a second.

5 This appears in the section of the report talking about
6 the obligations of the DEA. Do you see that?

7 **A.** Yes.

8 **Q.** So let's go back to Page 6. Would you expect the DEA
9 to meet their obligation to conduct reviews of the
10 functionality of McKesson's diversion compliance program?

11 **A.** Yes.

12 **Q.** All right. The next sentence says, "DEA shall also
13 review the investigatory files maintained by McKesson of the
14 customers serviced by the distribution centers subject to
15 the compliance reviews."

16 And let's just underline "review the investigatory
17 files" if we could at the end of the second highlighted line
18 from the bottom where it says "review the investigatory
19 files."

20 Would you expect the DEA to meet their obligation to
21 review the investigatory files maintained by McKesson of the
22 customers serviced by the distribution centers subject to
23 the reviews?

24 **A.** Yes.

25 **Q.** It goes on. Let's skip a sentence. It says, "During

1 the course of the compliance review, if requested McKesson
2 shall provide DEA with information related to the sales of
3 controlled substances, non-controlled drugs, and listed
4 chemicals from the effective date of the agreement to the
5 date of the compliance review by the particular distribution
6 center being reviewed."

7 Did I read that correctly?

8 **A.** Yes.

9 **Q.** Would you expect the DEA to ask where they thought it
10 was appropriate for -- and let's underline "sales of
11 controlled substances, non-controlled drugs, and listed
12 chemicals."

13 **A.** Yes.

14 **Q.** And then it says at the conclusion of each compliance
15 review, DEA shall conduct an exit interview with an
16 appropriate McKesson representative to provide DEA's
17 preliminary conclusions regarding the compliance review.

18 Do you see that reference to the exit interview?

19 **A.** Yes, I do.

20 **Q.** Do you know -- would you expect those exit interviews
21 to have occurred given this obligation in this Settlement
22 Agreement?

23 **A.** Yes.

24 **Q.** Do you know of any concerns raised in those exit
25 interviews with McKesson on any of these points, the

1 functionality of its diversion compliance program, the
2 investigatory files maintained, or any information requested
3 in these other categories?

4 **A.** No, I do not know personally.

5 **Q.** Let's look at Subsection (f), please. That's the next
6 section in the 2008 Settlement Agreement, Page 6 of Defense
7 West Virginia -- I'm sorry -- P-23733.

8 You were shown this sentence at the end that says, "A
9 finding of satisfactory does not otherwise express DEA's
10 approval of the compliance program implemented at any
11 particular distribution center."

12 Do you remember being shown that language yesterday?

13 **A.** Yes.

14 **Q.** Do you see where it says "does not otherwise express
15 approval"?

16 **A.** Yes.

17 **Q.** So let's look at what is being reviewed.

18 The first sentence says, "The compliance reviews will
19 be deemed satisfactory unless DEA determines that one or
20 more of the facilities being inspected has, one, failed to
21 maintain effective controls against diversion regarding the
22 distribution of any controlled substance."

23 Do you see that?

24 **A.** Yes.

25 **Q.** "Two, failed to detect and report to DEA suspicious

1 orders of controlled substances."

2 Do you see that?

3 **A.** Yes.

4 **Q.** Or, "Three, failed to meaningfully investigate new or
5 existing customers regarding the customer's legitimate need
6 to order or purchase controlled substances."

7 Do you see that?

8 **A.** Yes.

9 **Q.** Would you expect the DEA to carry out its
10 responsibilities to only deem these compliance reviews
11 satisfactory unless there's a finding of failure to maintain
12 effective controls, failure to detect and report suspicious
13 orders, or failure to meaningfully investigate new or
14 existing customers?

15 **A.** Yes, during that, during that snapshot period of
16 review, yes.

17 **Q.** And you know McKesson passed those compliance reviews;
18 correct?

19 **A.** Yes, during that snapshot period of review, yes.

20 **Q.** And you know of no concerns that the DEA raised on any
21 of these specific factors that they were reviewing in order
22 to deem the distribution center satisfactory?

23 **A.** Again, during that, that short time period of review,
24 yes, they did not find anything.

25 **Q.** I want to come back to a point we talked about before

1 the break. Did I hear you correctly that although it
2 doesn't appear in the regulation, you said in your
3 distributor letters that they were supposed to identify for
4 a suspicious order what the issue is with the pharmacy? Did
5 I understand that correctly? Remember I said I'll come back
6 to that?

7 **A.** Yeah. I -- they were supposed to explain what created
8 the suspicious nature of the order which is basically due
9 diligence.

10 **Q.** Were they -- sorry.

11 **A.** A suspicious order is not just, oh, it's over the
12 threshold. It could be over threshold because it's next to
13 a cancer center or palliative care center, a hospital.
14 There's got to be something just -- threshold, that's
15 exactly what due diligence is. It's looking at a suspicious
16 order above threshold. There's got to be some reason it's
17 above threshold. And that's got to be explained, yes.

18 **Q.** Did you testify before the break that you told
19 distributors in your letters that they had to identify what
20 the issue with the pharmacy was when they reported a
21 suspicious order to that pharmacy? Did you give that
22 testimony?

23 **A.** Yes, I believe I said the letters and/or -- I think it
24 was the letters or the distributor initiative briefings, but
25 I think I said letters, yes.

1 **Q.** I think you did too. So let's take a look at those
2 letters. Do you have in front of you P-32, sir? This is
3 the packet that contains the letters.

4 **A.** Yes.

5 **Q.** Okay. And go to Page 9. Do you see your
6 September 27th, 2006, letter?

7 **A.** I don't think it's in the 2006 letter.

8 **Q.** Okay. If you don't think it's there, let's go to the
9 December one. If you go to Page 3, do you see your
10 December 27th, 2007, letter?

11 **A.** Yes.

12 **Q.** Let's go to the second page, please, and if we can cull
13 out the second paragraph.

14 It states, "When reporting an order as suspicious,
15 registrants must be clear in their communications with DEA
16 that the registrant is actually characterizing an order as
17 suspicious."

18 Do you see that?

19 **A.** Yes.

20 **Q.** That's that idea you have to tell us you think it's
21 suspicious under your criteria; correct?

22 **A.** Yes.

23 **Q.** Is there anywhere in this letter where you tell them
24 you have to explain what it is about the pharmacy that makes
25 it suspicious?

1 **A.** That's due diligence. So, naturally, just over
2 threshold tells us nothing. It needs to be more than that.
3 No, in that letter, no, there's nothing. But we've
4 explained to them -- we explained to them in the distributor
5 initiative briefings what due diligence is.

6 **Q.** I'm not asking about due diligence, sir. I'm asking
7 about reporting suspicious orders. You did not attend the
8 due diligence briefings with McKesson, ABDC, or Cardinal;
9 correct?

10 **A.** That's correct.

11 **Q.** And in your letter, your letters, you do not tell
12 McKesson, ABDC, or Cardinal that they need to, when they
13 report suspicious orders, explain what it is about the
14 pharmacy that is triggering the report; correct?

15 **A.** Well, a suspicious order is specific on the pharmacy.
16 So it's not in that letter. However, --

17 **Q.** It's not in any of your letters, is it, sir?

18 **A.** No. Now that I -- I know it's not in the '6 one so --

19 **Q.** Okay. Let's, let's switch gears. I want to talk about
20 the closed system. Do you remember giving testimony that
21 was one of the stops, or several of the stops on the road
22 map, the closed system?

23 **A.** Yes.

24 **Q.** Let's go back to those stops on the road map. And I
25 want to start with the mission of the Office of Diversion

1 Control. And I'll give you a document I've marked as
2 Defense West Virginia 2408.

3 MR. SCHMIDT: May I approach, Your Honor?

4 THE COURT: Yes.

5 THE WITNESS: Thank you.

6 MR. SCHMIDT: Thank you.

7 BY MR. SCHMIDT:

8 **Q.** Do you have that in front of you, Defense West
9 Virginia 2408?

10 **A.** Yes.

11 **Q.** Do you recognize it as a printout from the Diversion
12 Control division at DEA that talks about their mission?

13 **A.** Yes.

14 MR. SCHMIDT: We move this into evidence, Your
15 Honor.

16 THE COURT: Any objection?

17 MR. ACKERMAN: The objection is foundation, Your
18 Honor. I don't know that -- it talks about the -- it's not
19 related to a time period where he was at DEA.

20 BY MR. SCHMIDT:

21 **Q.** Do you recognize this --

22 MR. SCHMIDT: I'll take care of that, Your Honor,
23 if I could.

24 BY MR. SCHMIDT:

25 **Q.** Look with me under "About Us." Do you see that?

1 **A.** Yes.

2 **Q.** Just read to yourself the mission of DEA. Do you see
3 that? Tell me when you've had a chance to read that.

4 (Pause)

5 **A.** Yes.

6 **Q.** Do you recognize that as the mission of the Office of
7 Diversion Control when you were at DEA?

8 **A.** Yes. That's a mission statement we used.

9 MR. SCHMIDT: I move it into evidence on that
10 basis, Your Honor.

11 MR. ACKERMAN: No objection.

12 THE COURT: It's admitted.

13 BY MR. SCHMIDT:

14 **Q.** So I want to break down that mission a little bit
15 and I want to start -- well, let me ask, do you
16 recognize this? It's a two-part mission, correct,
17 according to this mission statement?

18 **A.** Yes.

19 **Q.** I want to talk about both parts of that mission if I
20 could. Let me see if I can switch to the white board if
21 that's okay.

22 Do you still have that language in front of you, Mr.
23 Rannazzisi? I'm just going to write part of it up on the
24 screen if that's okay.

25 MR. SCHMIDT: Am I okay erasing this?

1 MS. SINGER: I think it's been saved. Excuse me.
2 I think it's been saved.

3 MR. SCHMIDT: Okay.

4 MR. ACKERMAN: Your Honor, I'm going to move over
5 there so I can see the board.

6 THE COURT: You may.

7 BY MR. SCHMIDT:

8 **Q.** All right. So looking with me at Exhibit 2408, is
9 part of the mission of the Office of Diversion Control
10 to prevent, detect, and investigate the diversion of
11 controlled pharmaceuticals and listed chemicals? Is
12 that one of the missions of Office of Diversion Control?

13 **A.** Yes, it is.

14 **Q.** I'm going to shorthand it by writing "prevent
15 diversion." And then it continues on and says, "while
16 ensuring an adequate and uninterrupted supply for legitimate
17 medical, commercial, and scientific needs."

18 Do you recognize that as the other mission of the
19 Office of Diversion Control?

20 **A.** Yes.

21 **Q.** Let me -- "while ensuring an adequate and uninterrupted
22 supply." And let me ask you about both halves of this
23 starting with preventing diversion.

24 In preventing diversion and in carrying out that
25 mission, the DEA is charged with protecting the public from

1 the harms of diversion; correct?

2 **A.** That is correct.

3 **Q.** In fact, one of the DEA's core functions is to prevent
4 the diversion of controlled substances into illicit
5 channels; correct? That's a core function of the DEA?

6 **A.** Yes.

7 **Q.** At the same time, and I think you talked about this in
8 some of your testimony yesterday particularly on quota, DEA
9 has a mission to ensure an adequate and uninterrupted supply
10 of controlled substances; correct?

11 **A.** That's correct.

12 **Q.** And you agree that it's vital that an adequate and
13 uninterrupted supply of pharmaceutical controlled substances
14 be available for effective patient care?

15 **A.** Yes.

16 **Q.** It's a public health concern when pharmacies cannot
17 dispense legitimate pharmaceutical controlled substances to
18 patients; correct?

19 **A.** To legitimate patients, yes.

20 **Q.** There can be no doubt that drug shortages adversely
21 affect the public health; correct?

22 **A.** That's, that's obvious, yes.

23 **Q.** All right. From your experience, you agree that when
24 it comes to the supply of prescription opioids, supply does
25 not drive demand?

1 **A.** Supply does not drive demand.

2 MR. ACKERMAN: Your Honor, while Mr. Schmidt is
3 writing, if it's at all possible for the Court to move that
4 to our screens, then I don't need to stand here with my
5 friends.

6 MR. SCHMIDT: Yeah, no objection, of course.

7 THE COURT: Yeah. Just find a good place there,
8 Mr. Ackerman.

9 MR. SCHMIDT: I'm sorry. Before you switch it,
10 the problem is that we may need to put up documents on the
11 individual screen.

12 MR. ACKERMAN: All right. I'll find a chair over
13 here.

14 MR. SCHMIDT: There's an empty one at my table.

15 (Laughter)

16 BY MR. SCHMIDT:

17 **Q.** Going back to this point, when it comes to demand
18 for prescription opioids, that comes not from supply but
19 from prescribing and dispensing in hospitals; correct?

20 **A.** No, not necessarily. Demand also -- when we're talking
21 about quota, it has things to do with research and
22 development, validation, export, things like that.

23 **Q.** When it comes to -- let me rephrase. When it comes to
24 demand, demand comes from things like prescribing,
25 hospitals, research and development, export; correct?

1 **A.** For that portion of the quota. Well, yeah, total, yes.

2 **Q.** The demand is driven by patient care and patient needs;
3 correct?

4 **A.** A large part of the quota is patient needs.

5 **Q.** Not by supply; correct? I didn't hear if you answered.
6 I apologize, sir. Not by supply; correct?

7 **A.** No, supply is not what drives demand.

8 COURT REPORTER: I'm sorry?

9 THE WITNESS: Demand drives the quota.

10 BY MR. SCHMIDT:

11 **Q.** Your understanding of what drives demand for
12 opioids is appropriate medical treatment; correct?

13 **A.** Yes, if -- appropriate medical treatment, yes.

14 **Q.** And prescription opioid levels in turn -- prescription
15 opioid levels in turn are based on the presumption that
16 medical need is legitimate; correct?

17 **A.** Yes. Appropriate medical treatment does drive some of
18 the demand, yes.

19 **Q.** And just because you have a supply of prescription
20 opioids does not mean the supply must be used; correct?

21 **A.** That's correct.

22 **Q.** Correspondingly, reducing supply doesn't necessarily
23 reduce demand; correct?

24 **A.** That's correct.

25 **Q.** All right. Now, in terms of supply level, you never

1 provided guidance at DEA to tell companies that for a given
2 dose or type of prescription opioid if they see doses above
3 that level, they should investigate, did you?

4 **A.** I personally didn't.

5 **Q.** Okay.

6 MR. SCHMIDT: May I approach, Your Honor?

7 THE COURT: Yes.

8 BY MR. SCHMIDT:

9 **Q.** I've passed you a document marked P-23594-001. Do
10 you know what this document is?

11 **A.** Yes. I believe these are the summary reports that we
12 put on the DEA website.

13 MR. SCHMIDT: I move this into evidence, Your
14 Honor.

15 THE COURT: Yes.

16 MR. ACKERMAN: No objection.

17 THE COURT: Did you move its admission?

18 MR. SCHMIDT: I did, Your Honor.

19 THE COURT: And there's no objection; right?

20 MR. ACKERMAN: No objection.

21 THE COURT: I was reading it and I wasn't paying
22 attention. It's admitted.

23 BY MR. SCHMIDT:

24 **Q.** All right. If we look at the cover of this
25 document, do you see it says "Department of Justice"?

1 And it's on your screen as well, just not on the big
2 screen.

3 **A.** Yes.

4 **Q.** And it says "ARCOS Report 4." Do you see that?

5 **A.** Yes.

6 **Q.** And it says reporting period January, 2010 to December,
7 2010. Do you see that?

8 **A.** Yes.

9 **Q.** And this is, this is that portion of the ARCOS data the
10 DEA reported to the public; correct?

11 **A.** Yes.

12 **Q.** And I've chosen this period of time because there's
13 been a focus on this period of time in terms of a high
14 level, or purportedly high level of prescription opioids
15 during this time period.

16 So let's -- having said that, let's look at Page 21 of
17 this report. Actually, let's start with Page 18. I
18 apologize.

19 And if we look at -- tell me when you're there, sir.

20 **A.** I believe I'm there.

21 **Q.** Okay. If you look at the left-hand side about
22 two-thirds of the way down, and if you can pull it up a tiny
23 bit, just pull up the screen a tiny bit. There we go.

24 It says U.S. grams per hundred thousand, Drug Code
25 9143, drug name hydrocodone [sic].

1 Do you see that?

2 **A.** Yes.

3 **Q.** Do you have an understanding that this is the DEA
4 reporting the average grams per hundred thousand people for
5 different states for oxycodone?

6 **A.** Based on ARCOS, yes.

7 **Q.** Correct?

8 **A.** It's the amount of drugs that ARCOS, on an ARCOS
9 analysis has gone into these states per 100,000.

10 **Q.** And if we look at West Virginia, West Virginia is 9.
11 Do you see that?

12 **A.** Yes.

13 **Q.** Let's go to 21. And, very quickly, do you see that 21
14 reports the same data for hydrocodone? This time West
15 Virginia at this point in time is number 7. Do you see
16 that?

17 **A.** Yes.

18 **Q.** When you were at DEA, did you ever issue guidance to
19 distributors, the healthcare community, doctors that these
20 levels were too high?

21 **A.** No, I did not.

22 **Q.** Are you aware that the DEA also publishes this data at
23 the zip code level?

24 **A.** I'm sorry?

25 **Q.** At the zip code level.

1 **A.** Yes, uh-huh.

2 MR. SCHMIDT: May I approach?

3 THE COURT: Yes. You should have bought stock in
4 International Paper, Mr. Schmidt.

5 MR. ACKERMAN: At some point, Your Honor, I'm sure
6 someone is going to object on behalf of the earth.

7 MR. SCHMIDT: Someone should. I'm happy to do
8 less.

9 BY MR. SCHMIDT:

10 **Q.** This is a lot of paper for a little point.

11 Do you see that this is 23591 and it's a similar retail
12 drug summary report, but this time by zip code within the
13 state? Do you see that?

14 **A.** Yes.

15 MR. SCHMIDT: We move this into evidence, Your
16 Honor.

17 THE COURT: Any objection?

18 MR. ACKERMAN: No objection.

19 THE COURT: It's admitted.

20 BY MR. SCHMIDT:

21 **Q.** Let's look at Page 354, please. Do you see that on
22 Page 354 -- I thought it said oxycodone on this page.
23 I'll represent to you that this is the oxycodone levels.
24 You can flip back in the report to confirm that.

25 Do you see the report of the oxycodone levels by zip

1 code on Page 354?

2 **A.** Yes.

3 **Q.** And if we look at zip codes 255 and 257, do you see
4 those zip codes?

5 **A.** Yes.

6 **Q.** And I'll represent to you that those zip codes include
7 Huntington and Cabell County, but they also include
8 additional areas. Is that something you were aware of?

9 **A.** No.

10 **Q.** Did DEA ever issue any guidance in connection with
11 issuing a report like this at any point in time to
12 healthcare providers, manufacturers, distributors,
13 pharmacies that specific levels at the zip code level were
14 too high?

15 **A.** No. DEA would not issue something like that.

16 **Q.** Did they ever say certain levels merited investigation?

17 **A.** No. The reason this is put on there is to help
18 healthcare providers, public health officials, law
19 enforcement, different organizations knowing what's going
20 into their systems. That's why it's on the DEA website.

21 **Q.** That was the intent, to let entities like the City of
22 Huntington and Cabell County know exactly what was going
23 into their communities?

24 **A.** Health departments, state health departments, things
25 like that. We wanted to get it out there about exactly

1 population wise how much drug is going into the areas.

2 **Q.** So that they could act as appropriate if they deemed it
3 appropriate?

4 **A.** The information was presented for their -- whatever
5 they deemed appropriate.

6 **Q.** Okay. I want to talk about some of the participants
7 now in the closed system that you touched on with the Court
8 yesterday and the day before.

9 Anyone who handles a controlled substance has to be
10 registered with the DEA; correct?

11 **A.** Except for nurses and pharmacists.

12 **Q.** Nurses have to operate under the direction of doctors;
13 correct?

14 **A.** Or hospitals.

15 **Q.** Or hospitals. And pharmacists have to be affiliated
16 with a pharmacy that's registered; is that correct?

17 **A.** Yes, uh-huh.

18 **Q.** And that DEA registration includes prescribers; right?

19 **A.** Yes.

20 **Q.** Prescribers can only write prescriptions for
21 prescription opioids if they're licensed with their state
22 but also if they're registered with the DEA; correct?

23 **A.** Yes.

24 **Q.** Did you have an understanding when you were at the DEA
25 as to why there's a separate requirement for DEA

1 registration in addition to the requirement that they be
2 licensed by the state?

3 **A.** So a DEA registration authorizes them to have a -- to
4 handle controlled substances. The state registration,
5 because they're licensed to practice medicine or whatever
6 they're practicing, and also there's a separate state
7 license for controlled substances but -- in some states.

8 So there's -- it's a two-part system. You've got to be
9 registered by the state. The state has to grant you a
10 license. And then DEA will come and grant you their
11 license.

12 **Q.** My question was a little different, sir. My question
13 was why is there a DEA requirement of a separate DEA
14 registration in order to prescribe controlled substances, if
15 you know? Why not just have the state requirement?

16 **A.** Because under the Controlled Substances Act it's
17 required.

18 **Q.** Do you know why?

19 **A.** Yeah, because the federal government wants to ensure
20 that controlled substances under the Act are being handled
21 appropriately.

22 **Q.** You understand that registration had to be renewed
23 every three years?

24 **A.** Yes.

25 **Q.** And just so -- actually, I'll skip moving in the

1 regulation.

2 Did you have an understanding when you were at DEA as
3 to why prescribers weren't simply given a lifetime
4 registration from DEA, why they had to be renewed every
5 three years?

6 **A.** To ensure that they're appropriately licensed and that
7 they did not have anything in their backgrounds during that
8 three-year period that could warrant them, you know,
9 disqualifying them from getting a license, a DEA
10 registration.

11 **Q.** I'm going to show you P-4215 if I could. I just
12 misread it. I apologize. It's P-42145.

13 MR. SCHMIDT: May I approach, Your Honor?

14 BY MR. SCHMIDT:

15 **Q.** Mr. Rannazzisi, do you recognize this as a DEA
16 regulation regarding prescriptions for controlled
17 substances?

18 **A.** Yes.

19 MR. SCHMIDT: We move this into evidence, Your
20 Honor.

21 THE COURT: Any objection?

22 MR. SCHMIDT: P, Plaintiffs' 42145.

23 MR. ACKERMAN: No objection.

24 THE COURT: It's admitted.

25 BY MR. SCHMIDT:

1 **Q.** In this regulation in the second sentence it
2 states, "The responsibility for the proper prescribing
3 and dispensing of controlled substances is upon the
4 prescribing practitioner."

5 Do you see that language?

6 **A.** Yes.

7 **Q.** And then it refers to a corresponding responsibility
8 with the pharmacist who fills the prescription; correct?

9 **A.** That's correct.

10 **Q.** And only a DEA registered practitioner may make the
11 determination if a controlled substance is medically
12 necessary; correct?

13 **A.** For a particular patient.

14 **Q.** Yes.

15 **A.** For prescribing, yes.

16 **Q.** And a distributor cannot make the determination if a
17 controlled substance is medically necessary for a particular
18 patient; correct?

19 **A.** Yes. And we've never asked a distributor to do that.

20 **Q.** Fair. In fact, yesterday you testified that you were
21 not asking distributors to become doctors and figure out
22 what's legitimate and what's not; correct?

23 **A.** That's correct.

24 **Q.** Yesterday you testified that you never required
25 distributors to look at what doctors were doing, questioning

1 a doctor's prescribing habits; correct?

2 **A.** That's correct.

3 **Q.** Why are DEA registered practitioners the only ones who
4 can make the determination that a medication is appropriate
5 for an individual patient?

6 **A.** Because they have to make a determination that the
7 medication that they're prescribing meets the needs, medical
8 needs of that particular patient. They're seeing that
9 patient. No one else is.

10 **Q.** Okay. Was there ever an occasion you know of where you
11 or someone at DEA told one of the distributors in this case
12 that they should stop supplying to a pharmacy in Huntington
13 or Cabell because of a DEA registered doctor whose
14 prescriptions were being filled at that pharmacy?

15 **A.** I've never done that, and I don't know of anybody among
16 the staff that has when I was there.

17 **Q.** You would agree with me that -- and I think you talked
18 about some of these statistics yesterday. I just want to
19 make sure we're on the same page.

20 During your time at DEA, 99.5 percent of prescribers
21 were not over-prescribing; correct?

22 **A.** Yeah, we used that number. We generally used
23 99 percent but we've gone to .5.

24 **Q.** And I don't want to quibble, but because I've written
25 99.5 on the board, do you want to see your congressional

1 testimony where you said that?

2 **A.** That's fine.

3 **Q.** You don't take issue with it; right?

4 **A.** We've used 99 percent too. It just depends on when
5 we're talking.

6 **Q.** Yeah, understood. And that's what I want to go to
7 next. You've actually said 99 percent of doctors are
8 perfect. Correct?

9 **A.** Yeah, I've said that they're doing things
10 appropriately, yes.

11 **Q.** That they're perfect; correct?

12 **A.** I don't recall saying "perfect," but I may have during
13 one presentation.

14 MS. SINGER: Objection, Your Honor. I don't think
15 what Mr. Schmidt wrote is what Mr. Rannazzisi just
16 testified.

17 MR. SCHMIDT: Let me see if I can cure that, Your
18 Honor.

19 BY MR. SCHMIDT:

20 **Q.** Defense West Virginia 620. Do you remember being
21 asked about giving congressional testimony at various
22 points in time, Mr. Rannazzisi?

23 MR. SCHMIDT: May I approach, Your Honor?

24 THE COURT: Yes.

25 THE WITNESS: Yes.

1 MR. SCHMIDT: If there's no objection, we'll start
2 doing excerpts on these bigger documents. It does seem a
3 waste to do all this for a small part at this point.

4 BY MR. SCHMIDT:

5 **Q.** If we look at Defense West Virginia 620, it's a
6 hearing before a House of Representatives Committee,
7 March 1st, 2012. Do you see that?

8 **A.** Yes.

9 **Q.** And then if we go to -- I'm using the numbers in the
10 lower left corner, Page 98. You'll see various comments
11 from you, including a larger one in the top half, right
12 barely above the top half of the page. Do you see that?

13 **A.** On page -- which page?

14 **Q.** Page 98 in the lower left-hand corner.

15 **A.** Yes, I've got it.

16 **Q.** And if you look at the second sentence there that
17 begins "the problem," do you see that? Do you see where you
18 say, "The problem is that the doctors continue," and then
19 you stop, "not all doctors, 99 percent of the doctors are
20 perfect."

21 Do you see that you said that before Congress?

22 **A.** Maybe I'm not on the right page then. What's the page
23 on top?

24 **Q.** The page on top is 94.

25 **A.** Okay. I'm there.

1 Q. And it's the third quote from you on the page right
2 before the halfway mark.

3 A. Okay. I see it. I see it.

4 Q. Do you see where you said to Congress 99 percent of the
5 doctors are perfect? Do you see that?

6 A. Yes.

7 Q. Were you trying to be accurate and correct in your
8 testimony to Congress?

9 A. I was giving an estimate on what DEA has said in the
10 past.

11 Q. Okay.

12 THE COURT: Do you still object, Ms. Singer?

13 MS. SINGER: I don't think it's worth the
14 objection, Your Honor, so I withdraw the objection.

15 MR. SCHMIDT: Thank you.

16 BY MR. SCHMIDT:

17 Q. You repeatedly stated, including to Congress
18 throughout your tenure, that the overwhelming majority
19 of prescribing in America is conducted responsibly.
20 Correct?

21 A. Yes.

22 Q. And during your tenure, you also said that the DEA
23 recognizes that nearly every prescription issued by a
24 physician in the United States is for a legitimate medical
25 purpose in the usual course of professional practice;

1 correct?

2 **A.** Where, where did I say that? I've got to go back and
3 look at that.

4 **Q.** Okay. Let's take a look at that.

5 MR. SCHMIDT: May I approach, Your Honor?

6 THE COURT: Yes.

7 BY MR. SCHMIDT:

8 **Q.** This is a statement from the Federal Register
9 DEA -- while you were at DEA. Do you see that?
10 September 6th, 2006?

11 **A.** Yes.

12 **Q.** Okay.

13 MR. SCHMIDT: We move this into evidence, Your
14 Honor, Defense West Virginia 3076.

15 THE COURT: Any objection to this one?

16 MR. SCHMIDT: Actually, this is in evidence.
17 Nevermind.

18 THE COURT: Oh, it's in evidence.

19 MR. SCHMIDT: I'm sorry.

20 BY MR. SCHMIDT:

21 **Q.** Let's go to the second page.

22 **A.** Uh-huh.

23 **Q.** On the second page in the upper left corner it says,
24 "Drug Enforcement Administration." And it says "Action:
25 Policy Statement." Do you see that this is a policy

1 statement of the DEA while you were there?

2 **A.** Yes, sir. I was -- yes, sir.

3 **Q.** It's a policy statement regarding, quote, dispensing
4 controlled substances for the treatment of pain. Do you see
5 that?

6 **A.** Yes.

7 **Q.** And it's a policy statement, if we look for further
8 information -- if we look -- strike that. If we look a
9 little further down, it says, "For further information,
10 contact." Do you see that?

11 **A.** Yes.

12 **Q.** And it has someone in the Office of Diversion Control,
13 the office you oversaw. Do you see that?

14 **A.** Yes.

15 **Q.** And did you supervise this person, Mr. Caverly?

16 **A.** Yes.

17 **Q.** Were you responsible for this policy statement when it
18 came out?

19 **A.** We were a part of drafting of this policy statement,
20 yes.

21 **Q.** Okay. So let's look at this policy statement. This is
22 one of those documents that we talked about yesterday with
23 Ms. Singer that were issued to give guidance to doctors and
24 others. Right?

25 **A.** I've got to re-read this policy statement. I -- it's a

1 policy statement regarding the treatment of pain, if I'm not
2 mistaken.

3 **Q.** Okay.

4 **A.** But I have to go back and read it. If this is the same
5 one I'm thinking about, it's very detailed and there's a lot
6 of information. So I would have to go back and read this.

7 But --

8 **Q.** Okay.

9 **A.** So let me just -- with that caveat.

10 **Q.** Okay. Let me see if I can help you. Let's go to the
11 second page on the right-hand column. And it says -- you've
12 got it on the screen.

13 It says "Purposes and structure of this document." Do
14 you see that?

15 **A.** Yes.

16 **Q.** And this document came from the Office of Diversion
17 Control; correct?

18 **A.** It -- well, it came from the administrator. The
19 administrator signed the document.

20 **Q.** You had a role in this document; correct?

21 **A.** I was at the Office of Diversion Control during this
22 time period.

23 **Q.** Did you have a role in this document?

24 **A.** I, I reviewed the document, yes.

25 **Q.** One of the chief purposes of the document is to make

1 clear that the long-standing requirement under the law that
2 physicians may prescribe controlled substances only for
3 legitimate medical purposes in the usual course of
4 professional practice should in no way interfere with the
5 legitimate practice of medicine or cause any physician to be
6 reluctant to provide legitimate pain treatment.

7 Do you see that?

8 **A.** Yes.

9 **Q.** This was giving guidance to doctors; right?

10 **A.** Yes.

11 **Q.** All right. And then if we go to Page 7, please, in the
12 lower left corner, and tell me when you're there.

13 **A.** Okay.

14 **Q.** And I'm going to direct your attention to the
15 right-hand column right before the bolded heading which we
16 have up on the screen. And it has that language I started
17 off by reading.

18 "To the contrary, the agency recognizes that nearly
19 every prescription issued by a physician in the United
20 States is for a legitimate medical purpose in the usual
21 course of professional practice."

22 Was that stated in the policy statement from the DEA
23 when you were at the DEA running the Office of Diversion
24 Control?

25 **A.** Yeah. I don't remember that statement but, again, I

1 know this document was not just -- it was published as a DEA
2 document, but there were other, other agencies and
3 government agencies and entities involved in this document.

4 **Q.** Okay. But you see where it says nearly every
5 prescription -- and I'm going to write Rx for short -- is
6 for a legitimate medical purpose. Do you see that?

7 **A.** Yes.

8 **Q.** Do you take issue with this as a true statement, sir?

9 **A.** From -- I would say, I would say the vast majority of
10 the prescriptions. I wouldn't say nearly every. Nearly
11 every is pretty, pretty focused. I don't think that's the
12 case.

13 **Q.** Did you ever take any steps to repudiate this statement
14 in an official DEA policy statement on your watch?

15 **A.** Again, it's official policy statement that was made by
16 not only DEA but the department and other entities within
17 the United States government. It just was a vehicle. The
18 DEA Federal Register was the vehicle to get that out.

19 **Q.** Do you mind answering my question now, sir?

20 **A.** Which is?

21 **Q.** Did you take any steps to repudiate that statement
22 while you were at DEA?

23 **A.** I don't recall taking any steps to retract or repudiate
24 the statement.

25 **Q.** Okay. In the same document you talked about the idea

1 of doctors acting improperly, and I want to direct your
2 attention to that.

3 Could we go to Page 5 of this document. And tell me
4 when you're there.

5 Let's cull up the right-hand column, just the heading.

6 **A.** Okay. I'm on Page 5.

7 **Q.** Can we cull up Page 5, Defense West Virginia 3076, so
8 we're all looking at the same thing. Is it available to put
9 up on the screen? Thank you.

10 And while we do, let me read the title in the record,
11 the heading -- I'm sorry -- of this subsection.

12 It says, "The number of physicians who prescribe
13 controlled substances in violation of the CSA --" and now we
14 see it on the screen -- "is extremely small and there is no
15 DEA crackdown on physicians."

16 Do you see that in this policy statement that when it
17 comes to the physicians who prescribe controlled substances
18 in violation of the CSA, that is extremely small? Do you
19 see that?

20 **A.** Yes, as compared to the patient population, yes, the
21 physician population, prescriber population, yes.

22 **Q.** That's a true statement; right?

23 **A.** Yes.

24 **Q.** And it then goes on to characterize that. It has that
25 "overwhelming majority" language you and I have talked

1 about. DEA recognizes that the overwhelming majority of
2 American physicians who prescribe controlled substances do
3 so for legitimate medical purposes.

4 Do you see that?

5 **A.** Yes.

6 **Q.** In fact, the overwhelming majority of physicians who
7 prescribe controlled substances do so in a legitimate manner
8 that will never warrant scrutiny by federal or state law
9 enforcement officials. Do you see that?

10 **A.** Yes.

11 **Q.** And is that a true statement?

12 **A.** Yes.

13 **Q.** And then you quantify actions against doctors in the
14 italicized sentence, if we can scroll down in this column,
15 please.

16 Do you see a little further down there's an italicized
17 sentence? Do you see that?

18 **A.** Yes.

19 **Q.** "In any given year, including 2005, fewer than one out
20 of every 10,000 physicians in the United States (less than
21 .01 percent) lose their controlled substance registrations
22 based on a DEA investigation of improper prescribing."

23 Did I read that correctly?

24 **A.** Yes.

25 **Q.** Is that accurate that in a given year less than

1 .01 percent of physicians in the United States lose their
2 controlled substance registration based on a DEA
3 investigation of improper prescribing?

4 **A.** Back in 2005 and prior to, yes.

5 **Q.** Was that true in 2007 when you gave the same testimony
6 before Congress?

7 **A.** I'm not sure in 2007 if that's true or not. I would, I
8 would guess that the numbers -- I just don't recall. But,
9 but this is specific to prior to 2005. So if there's some
10 other document or -- I've looked at it, but I just don't
11 recall saying that except for 99 percent of the prescribers.
12 Generally, 99 percent of the prescribers are doing exactly
13 what they're told to do.

14 MR. SCHMIDT: May I approach, Your Honor?

15 THE COURT: Yes.

16 MR. SCHMIDT: Actually, can we just put it up on
17 the screen because it's impeachment? We have it here.

18 THE WITNESS: Thank you.

19 MR. SCHMIDT: You're welcome.

20 BY MR. SCHMIDT:

21 **Q.** I've passed you MC-WV-2172, testimony before House
22 of Representatives Subcommittee on July 12th, 2007. Do
23 you see that?

24 **A.** Yes.

25 **Q.** If you go to Page 11 in the bottom left-hand corner

1 you'll see a prepared statement from you read into the
2 record. Do you see that?

3 **A.** Yes.

4 **Q.** And if you go to Page 12, the fifth full paragraph,
5 generally speaking, do you see you again in July of 2007
6 saying, "In any given year DEA arrests less than .01 percent
7 of the 750,000 doctors registered with the DEA for a
8 criminal violation." Do you see that?

9 **A.** Yes. That's specific to a criminal violation.

10 **Q.** Okay.

11 **A.** That's what it says, a criminal violation.

12 **Q.** Okay.

13 **A.** It doesn't say anything about administrative actions.

14 **Q.** I'm not going to ask you about those further. Do you
15 want me to take back any of those large documents?

16 **A.** I would love for you to take back some of these large
17 document.

18 **Q.** That's the only time you'll ever say that to me. But
19 the testimony, if you want to give me that, all the
20 suspicious order reports, if you want to give me those.

21 **A.** Yes.

22 **Q.** All right. So if we go back to this 2006 policy
23 statement from DEA, Defendants' West Virginia 3076, I want
24 to go back to Page 5, please. And let's look at that
25 italicized sentence we were highlighting.

1 Have you ever publicly identified what percentage of
2 opioid prescriptions in a given year are written by this
3 .01 percent versus the remaining 99.9 percent? Is that
4 something you've ever quantified for the public?

5 **A.** No.

6 **Q.** Do you know if any of the doctors in Huntington or
7 Cabell on your watch were in this .01 percent?

8 **A.** I do not know.

9 **Q.** And when you identified those .01 percent who lost
10 their registrations on the other example were criminally
11 prosecuted, did you make that determination just by looking
12 at their prescribing levels or did you require more
13 information?

14 **A.** Oh, it would require an investigation, a full
15 investigation.

16 **Q.** Did you ever have a criteria that if a doctor fell
17 within the top one percent, they would automatically be
18 investigated in terms of their prescribing levels?

19 **A.** Doctors are investigated based on a specific set of
20 facts. And after that, you know, we get into an
21 investigative process.

22 **Q.** My question was simply was there ever --

23 **A.** I'm sorry. I said doctors investigated by specific --
24 it's fact-based, specific set of facts. So we don't
25 investigate based on quantities.

1 **Q.** You answered my question. Thank you. You looked at a
2 range of factors to determine --

3 **A.** A range of factors, yes.

4 **Q.** A range of factors beyond simply quantity; correct?

5 **A.** Yes, for doctors, yes.

6 **Q.** Yes. Now, the DEA made these statements about
7 prosecutions being rare in the context of wanting to
8 encourage doctors that they could prescribe prescription
9 opioids as medically appropriate without being concerned
10 about the DEA cracking down on them; correct?

11 **A.** We wanted to assure doctors that if they were
12 prescribing appropriately, they would never have problems
13 with DEA as long as they were prescribing for legitimate
14 medical purpose in the usual course of professional
15 practice.

16 **Q.** In fact, if we look at -- if we look at the document we
17 were just looking at 3076-5, the policy statement, the
18 language we were just looking at, the heading, Page 5, that
19 heading says there is no DEA crackdown on physicians;
20 correct?

21 **A.** I don't know where -- this is not --

22 **Q.** It's Page 5 on the right-hand side, the boldfaced
23 heading.

24 **A.** Page 5, right-hand side.

25 **Q.** There is no crackdown -- no DEA crackdown on

1 physicians. That's what you were reassuring doctors of;
2 correct?

3 **A.** Yes.

4 **Q.** And you've said in your testimony before Congress that
5 doctors should not hesitate and should continue to provide
6 patients with whatever treatment they feel appropriate as
7 long as it's for a legitimate medical purpose and done in
8 the usual course of medical practice; correct?

9 **A.** That's the standard, yes.

10 **Q.** And let's go to Page 6 in this document, Defense West
11 Virginia 3076. In the upper left-hand corner it states, "It
12 would be a disservice to many patients if exaggerated
13 statements regarding the likelihood of a DEA investigation
14 resulted in physicians mistakenly concluding that they must
15 scale back their patient's use of controlled substances to
16 levels below that which is medically appropriate."

17 That's a true statement; correct?

18 **A.** Back in 2006, yes.

19 **Q.** And just to be clear, there was an opioid crisis in
20 2006; correct?

21 **A.** There was, yes.

22 **Q.** Now, you gave specific guidance in this document;
23 correct?

24 **A.** I'm, I'm not sure where -- if you point it to me, I'm
25 more than happy to read it.

1 **Q.** Sure. Let's go to Page 9, please, Defense West
2 Virginia 3076. If we could blow up the top in the middle
3 column, please.

4 Do you see in the top of the middle column, if you want
5 to read to yourself the language that precedes that in the
6 prior column. I'm going to focus on the second line.

7 Do you see that it says, "Courts have recognized that
8 prescribing an inordinately large quantity of controlled
9 substance can be evidence of a violation of the CSA."

10 Do you see that?

11 **A.** Yes.

12 **Q.** And that's this idea about having exceptionally high
13 levels; correct?

14 **A.** Yes.

15 **Q.** And then I want to read what you write below that if we
16 can scroll down in this paragraph.

17 The next paragraph begins, "Nonetheless, the amount of
18 dosage units per prescription will never be a basis for
19 investigation for the overwhelming majority of physicians."

20 Do you see that?

21 **A.** Yes.

22 **Q.** That's a true statement; correct?

23 **A.** Back in 2006, that was a very true statement.

24 **Q.** Was this statement in this DEA policy statement in 2006
25 ever repudiated on your watch?

1 **A.** Well, remember, as I said before, this is not a -- this
2 is not just a DEA state policy statement. There were other
3 agencies involved in this including the Department of
4 Justice. DEA was the vehicle to get that out. If you
5 notice, I did not sign the policy statement. It was signed
6 by the administrator of the Drug Enforcement Administration.

7 **Q.** Do you know if DEA --

8 **A.** That was a statement.

9 **Q.** Do you know if it's ever been repudiated by DEA?

10 **A.** I never repudiated it. I have no idea if it was ever
11 repudiated after I left.

12 **Q.** Okay. Fair enough. Let's scroll down in this
13 paragraph. After saying that the amount will never be the
14 basis for investigation for the overwhelming majority of
15 physicians, if we go a sentence down, it states, "In rare
16 cases, it is possible that an aberrant physician could
17 prescribe such an enormous quantity of controlled substances
18 to a given patient that this alone will be a valid basis for
19 investigation."

20 Do you see that statement?

21 **A.** Yes.

22 **Q.** That was true when it was made; correct?

23 **A.** It was, it was -- if it's in this document, it was true
24 at the time.

25 **Q.** Okay. And then it gives an example. And before

1 looking at the example, let's scroll down to see what it
2 says after the example.

3 Could we look at the sentence beginning "again" a few
4 lines down? If you take that down and go to the middle
5 column, please. And probably 10 lines from the bottom, four
6 words in it begins "again, however," just above where your
7 cursor is in the middle column. "Again, however, such cases
8 are extremely rare." Can you cull that out?

9 Do you see where after giving this example of when
10 levels might be excessive it says, "Again, however, such
11 cases are extremely rare." Do you see that?

12 **A.** Yes.

13 **Q.** It continues, "The overwhelming majority of physicians
14 who conclude that use of a particular controlled substance
15 is medically appropriate for a given patient should
16 prescribe the amount of that controlled substance which is
17 consistent with their sound medical judgment and accepted
18 medical standards without concern that doing so will subject
19 them to DEA scrutiny."

20 Do you see that?

21 **A.** Yes.

22 **Q.** Okay. So when we were looking at this language, we
23 skipped over the example that was given. I want to go back
24 now to that example that was just above that.

25 And, so, this is an example of when, in the words of

1 the preceding sentence, there is such an enormous quantity
2 of controlled substances to a given patient that this alone
3 will be a valid basis for investigation, for example.

4 Do you see that language?

5 **A.** Yes.

6 **Q.** And the example provided of when there might be -- in
7 this 2006 DEA policy document of when there might be such an
8 enormous quantity of controlled substances to a given
9 patient that this alone will be a valid basis for
10 investigation is if a physician were to prescribe 1,600
11 tablets, and let's underline "1,600," per day, underline
12 "per day," of a Schedule II opioid to a -- and let's
13 underline "single patient." Do you see that?

14 **A.** Yes.

15 **Q.** And am I correct that this is the only example provided
16 in this DEA policy document to doctors and the healthcare
17 community of what constitutes such an enormous quantity of
18 controlled substances to a given patient that this alone
19 will be a valid basis for investigation? I don't see any
20 other examples. Do you?

21 **A.** I, I don't know. I'd have to go through.

22 **Q.** If you need to look, take a look. I'm representing
23 that there are none.

24 **A.** Okay. Well, I trust you. Well, --

25 (Laughter)

1 MR. ACKERMAN: Move to strike, Your Honor.

2 MR. SCHMIDT: I think he struck it himself, a
3 moment of candor taken back.

4 THE WITNESS: No, there's other, there's other
5 examples in here. I have to read the examples, but there
6 are other examples.

7 BY MR. SCHMIDT:

8 Q. Show me the examples that -- and I'm focused on
9 something specific.

10 A. I know. But I don't know until I read the examples.
11 You have the Smith example, the Bischoff example, the
12 Poulter example, looks like Singh. So there's other,
13 there's other examples here.

14 Q. Okay. And that's why I tried to tailor my question,
15 sir.

16 A. Okay.

17 Q. See where it talks about in rare cases it is possible
18 that an aberrant physician could prescribe such an enormous
19 quantity of controlled substances to a given patient that
20 this alone will be a valid basis for investigation? Do you
21 see that?

22 A. No, I understand that. But I think to, to, to --
23 without looking at these other cases, I don't know what the
24 quantities were in these cases and I don't know what the
25 cases -- the foundation of the cases were. So if I agree to

1 that, I mean, I don't think that would be doing the Court
2 justice.

3 **Q.** Fair enough. Let's stick to the example we see here on
4 the page where it says "for example" right before saying,
5 "Again, such cases are extremely rare."

6 **A.** Okay.

7 **Q.** 1,600 per day for a single patient. Do you see that?

8 **A.** Yes.

9 **Q.** Do you know why DEA in this policy statement that you
10 had a part in didn't say if a physician were to prescribe
11 100 tablets per day of a single opioid to a single patient,
12 that would certainly warrant investigation?

13 **A.** Again, I'm not sure why this was in there.

14 **Q.** Okay.

15 **A.** But I can tell you the Office of Diversion Control
16 doesn't necessarily go by quantity, but they always
17 investigate pursuant to legitimate medical -- prescribing
18 for a legitimate medical purpose in the usual course of
19 professional practice.

20 And while quantity is not an issue, we do look at other
21 factors that would open that investigation, and quantity
22 would be part of that once the investigation is opened.

23 **Q.** Do you know why the DEA didn't say 1,000 pills a day
24 for a single patient would certainly warrant investigation?

25 **A.** I don't know. But it looks like they were just looking

1 at trying to explain some egregious quantity. I don't know
2 what the thought process was of the person that wrote this
3 section.

4 **Q.** You agree with me that -- and I can give you a
5 calculator if you want. If you multiply 1,600 by 365 days,
6 by my math you get about 584,000 pills from a single doctor
7 to a single patient in this example.

8 **A.** Well, I trust your math.

9 **Q.** Let me just check it myself just to be sure. 584 --
10 I'm sorry. Let me do again because I might have gotten it
11 wrong. 584,000.

12 Did you ever tell doctors -- let's take a smaller
13 number -- that if they wrote half a million pills to a
14 single patient in a single year that in the words of this
15 guidance, that would certainly warrant an investigation as
16 there is no conceivable medical basis for anyone to ingest
17 that quantity of such a powerful narcotic? Did you ever
18 give that guidance, that half a million instead of 584,000?

19 **A.** I'm sorry. You're going to have to repeat that.

20 **Q.** Sure. At DEA are you aware of DEA ever giving
21 doctors -- we're talking about 584,000 pills a year here;
22 correct?

23 **A.** Okay.

24 **Q.** Did you ever give guidance to doctors that a lesser
25 amount, half a million pills in a year, would certainly

1 warrant investigation?

2 **A.** No, we didn't give guidance. But, obviously, 1,600
3 pills a day is almost an impossible quantity for opioids.
4 It is an impossible quantity. It's a ludicrous quantity.

5 So I think what they were doing was saying here's an
6 example and just throwing up a number that is so unrealistic
7 that no one would ever meet that.

8 **Q.** So other than giving an example that is impossible,
9 ludicrous, and so unrealistic as what would certainly
10 warrant investigation, is there any realistic possible
11 non-ludicrous number that the DEA gave doctors that in the
12 words of this policy statement from 2006 would certainly
13 warrant investigation?

14 **A.** I'm not aware of any.

15 **Q.** Are you aware -- actually, one more thing on this
16 document. This was a publicly available document; correct?
17 That's why it's in the Federal Register; right?

18 **A.** Yes.

19 **Q.** If we go to Page 5, back to Page 5, 3076, Page 5, that
20 right-hand column, I missed a sentence at the very end of
21 the paragraph we were looking at on the right-hand side.
22 It's the sentence before the final sentence. It's --
23 further down, if you could just scroll down. Right there.
24 A little, a little -- no, stop. A little up. Thanks.
25 That's perfect.

1 Do you see where it says, where it says, "Moreover, as
2 mentioned above, the responsibility for monitoring and
3 preventing controlled substance abuse is shared by state and
4 federal governments." Do you see that?

5 **A.** Yes.

6 **Q.** Is that a true statement?

7 **A.** Yes.

8 **Q.** Now, are you aware that DEA promoted pain relief at
9 various points in time while you were there?

10 **A.** I'm aware that -- we never promote pain relief. We
11 just support -- we, we -- I think the statement we've used
12 in the past was we never would want a patient to go without
13 pain relief.

14 **Q.** Well, let me ask you this question. Obviously, one of
15 your goals is preventing the abuse of pain medication;
16 correct?

17 **A.** Yes.

18 **Q.** Did you balance that with the policy of promoting pain
19 relief?

20 **A.** Again, we, we told -- we made numerous statements about
21 that saying that patients should get the appropriate medical
22 care to relieve their pain. We've said that over and over
23 again.

24 **Q.** I'm focusing on the verbiage I'm using. That was the
25 policy of promoting pain relief; correct?

1 **A.** It was a policy -- yeah, I guess if you want to call it
2 that, but it's a policy of treating pain appropriately.

3 **Q.** Okay. And that's something -- that policy of promoting
4 pain relief is something you've testified about in Congress;
5 right?

6 **A.** Yes.

7 **Q.** And, so, just within this document, let's look at what
8 this document says on that point.

9 If we could go to 3076, Page 4 please. And if you look
10 at the bottom of the left-hand column carrying over to the
11 center column, there's a reference to an interim policy
12 statement published in the Federal Register. Do you see
13 that?

14 **A.** Yes.

15 **Q.** And that's an interim policy statement from 2004 by the
16 DEA; correct?

17 **A.** Yes, I -- if I'm not mistaken, that one was withdrawn
18 from the -- we withdrew that.

19 **Q.** And I'm going to come to that. It says, "Chronic pain
20 is a serious problem for many Americans. It is crucial that
21 physicians who are engaged in legitimate pain treatment not
22 be discouraged from providing proper pain medication to
23 patients as medically justified."

24 Do you see that?

25 **A.** Yes.

1 **Q.** Okay. And this policy statement covered a lot of
2 things that I'm not going to go through. But I want to
3 focus on these two sentences.

4 Do you agree that those two sentences remained true
5 throughout your tenure at DEA; the recognition that chronic
6 pain is a serious problem for many Americans and that it is
7 crucial that physicians who are engaged in legitimate pain
8 treatment not be discouraged from providing proper
9 medication to patients as medically justified?

10 **A.** I agree that the second sentence is correct. The first
11 sentence -- I believe they've made different statements
12 about chronic pain and, and -- regarding the number of
13 chronic pain patients and the type of pain that's chronic
14 pain. Over the tenure that I had in the Office of Diversion
15 Control, that's changed considerably. So I don't
16 necessarily agree with that first statement.

17 **Q.** Let me just show you a document, Defense West Virginia
18 2640.

19 MR. SCHMIDT: May I approach, Your Honor?

20 THE COURT: It might be an appropriate time to
21 quit if you're at a good stopping point.

22 MR. SCHMIDT: Sure, of course, yes.

23 THE COURT: We've got to clear things out so I can
24 do another hearing. So we'll be in recess until 2:00.

25 (Recess taken at 11:56 a.m.)

1 THE COURT: Okay, Mr. Rannazzisi, you can resume
2 your seat there, sir.

3 MR. SCHMIDT: May I continue?

4 THE COURT: Yes.

5 MR. SCHMIDT: Mr. Rannazzisi, before we pick back
6 up, two housekeeping matters.

7 First, just if we can for you and the Court, somebody
8 pointed out to me on the break, when I wrote this first
9 line, supply does not drive demand, I left out the word
10 "drive".

11 Second, I did try to spend time over our lunch break
12 reducing so we can get you out of here and that includes
13 cutting out the exhibit I was about to ask you about. So,
14 let me take up a new topic, if I could.

15 May I approach to give out MCWV-2174?

16 THE COURT: Yes.

17 MR. SCHMIDT: Thank you, Your Honor.

18 BY MR. SCHMIDT:

19 **Q.** You have in front of you MCWV-2174?

20 **A.** Yes.

21 **Q.** Do you recognize this as a DEA write-up on a regulation
22 that it was issuing during your tenure or a rule that it was
23 issuing during your tenure?

24 **A.** Yes.

25 MR. SCHMIDT: We'd move this into evidence, Your

1 Honor.

2 MR. ACKERMAN: No objection.

3 THE COURT: It's admitted.

4 BY MR. SCHMIDT:

5 Q. Let's just orient us to what we're looking at here.
6 And before we get into this, is it correct that DEA took
7 steps on your watch to make it easier for doctors to
8 prescribe prescription opioids for longer periods of time
9 without seeing the patient in between?

10 A. It wasn't necessarily the prescription opioids.
11 Actually, this had to do more so with patients who were away
12 at school who were on ADHD medication, if I was not
13 mistaken.

14 Q. Okay. Well, let's look at what this says. If we go to
15 the first page, it says issuance of multiple prescriptions
16 for controlled substances. Do you see that language in
17 bold? And then it says agency, Drug Enforcement
18 Administration; action, final rule. Do you see that?

19 A. Yes.

20 Q. We can actually -- I'm going to switch over on the
21 screen, if I may, because we're done with this board.

22 And Schedule II controlled substances includes
23 oxycodone, correct?

24 A. Yes.

25 Q. After 2014, it included hydrocodone?

1 **A.** Yes.

2 **Q.** And this rule remained in place throughout your tenure
3 at DEA, correct?

4 **A.** Yes.

5 **Q.** Let's look at the summary. If we read the summary, it
6 says the Drug Enforcement Administration is finalizing a
7 notice of proposed rule making published in 2006. Do you
8 see that?

9 **A.** Yes.

10 **Q.** In that document DEA proposed to amend its regulations
11 to, quote, "allow practitioners to provide individual
12 patients with multiple prescriptions" -- and let's just
13 highlight that language -- "allow practitioners to provide
14 individual patients with multiple prescriptions to be filled
15 sequentially for the same Schedule II controlled substance,
16 with such multiple prescriptions having the combined effect
17 of allowing a patient to receive over time up to a 90-day
18 supply of that controlled substance." Did I read that
19 correctly?

20 **A.** Yes.

21 **Q.** So, in simple terms what this did is, you could go see
22 a doctor one time and instead of having to go back within a
23 90-day window, you could get back-to-back prescriptions to
24 cover you for up to 90 days, correct?

25 **A.** That's correct.

1 Q. And that was any Schedule II controlled substance,
2 correct?

3 A. Yes.

4 Q. And that lengthened the period of time that a patient
5 could go while having a controlled II Scheduled substance
6 without having to see their doctor, correct?

7 A. Yes.

8 Q. And this change was not limited to any specific
9 practitioners, but applied to all DEA registered
10 practitioners, correct?

11 A. That's correct.

12 Q. Dentists?

13 A. Well --

14 Q. General practitioners if they had a DEA registration?

15 A. And if the State allowed it.

16 Q. Correct.

17 A. Yes.

18 Q. So, let me be sure to add that. If the State allowed
19 it and they had a DEA registration, whether they were a
20 dentist or a general practitioner, this extension of time
21 applied to all of them?

22 A. Yes.

23 Q. Let's look at Page 7. Do you see where it says
24 conclusion? And in the second sentence it says as DEA noted
25 previously, this rule making was supported by a wide variety

1 of individuals and organizations, medical professionals,
2 patient advocacy organizations, and patients themselves. To
3 reiterate, the majority of commentators believed this final
4 rule would be beneficial from both physical and financial
5 perspectives, citing the time and money saved due to less
6 frequent -- I'm sorry -- less frequent visits to prescribing
7 practitioners, and the reduced physical toll resulting from
8 the reduced visits. Did I read that correctly?

9 **A.** Yes.

10 **Q.** What was your role in this rule?

11 **A.** I reviewed the rule and gave my input and then it was
12 -- subsequently went through the rule making process.

13 **Q.** Did you support it?

14 **A.** Yes, I did.

15 **Q.** And when you were saying college kids taking ADHD
16 medications, do you understand when it references physical
17 toll, that's talking about pain patients and prescription
18 opioids, correct?

19 **A.** Not necessarily.

20 **Q.** Is there a physical toll from college kids having to go
21 to their doctor?

22 **A.** Well, if they're four states over and they have to go
23 back every month, it would be difficult.

24 **Q.** Okay.

25 **A.** But that's not the only reason. This -- this

1 supplemented what the doctors were doing to begin with,
2 which was the doctors were prescribing huge quantities of
3 opioids so that patients wouldn't have to come back for --
4 every 30 days, especially palliative care, and Hospice care,
5 end of life care. Those people can't come back every
6 30 days.

7 So, what the doctors were doing, instead of prescribing
8 a hundred tablets, they were prescribing 300 tablets at that
9 moment in time. We thought that it would not be prudent to
10 have those tablets, if the patient passed, in somebody's
11 medicine cabinet.

12 So, if you have the do-not-fill, every 30 days it would
13 go back to the pharmacy, and every 30 days that pharmacy
14 would be authorized to fill. But this was all about keeping
15 huge quantities out of prescriptions and there's no quantity
16 limit. Congress never set a quantity limit on a Schedule II
17 prescription. So, they could have prescribed 300 tablets
18 easy. 400 tablets easy.

19 This cut down the amount of drugs that could be in the
20 house at any time and made sure that the patients would be
21 -- have access to the drugs, yet not keep a huge amount in
22 -- in their medicine cabinets, in their homes, because of
23 the prescriptions. And the same thing with the ADHD kids
24 that were over at school.

25 **Q.** So, a few follow-up questions, sir. First question,

1 this was not limited to palliative care, correct?

2 **A.** It was not.

3 **Q.** It did not set a pill limit to say we're going to
4 90 days, but that means you have to have a pill limit, did
5 it?

6 **A.** No. There was a pill limit. It's a 30-day -- it's a
7 90-day supply, if I'm not mistaken. So, there is a pill
8 limit.

9 **Q.** It was limited to 90 days, correct?

10 **A.** Right.

11 **Q.** It didn't limit the number of pills that could be
12 prescribed in those 90 days, correct?

13 **A.** Well, if it's a 90-day supply, it would be based on the
14 way it was -- if I'm not mistaken, I haven't read this in
15 awhile, but the way it was written, it would be per
16 prescription. So, the quantity in the prescription, saved
17 in the prescriptions, would dictate the amount.

18 **Q.** There was no limit on the prescription amount that
19 could be issued within that 90 days, correct?

20 **A.** It's been awhile. I have not read it. But if I
21 remember correctly, the whole reason for this was to limit
22 the amount of drugs per prescription so the doctor wouldn't
23 write for a 90-day supply in one prescription.

24 **Q.** I hear what you're saying. My question is simply there
25 was no limit in this rule on the number of prescriptions?

1 **A.** Again, if you --

2 THE COURT: Mr. Ackerman?

3 MR. ACKERMAN: Asked and answered, Your Honor.

4 MR. SCHMIDT: I don't think he's answered, Your
5 Honor. He's explained why he was trying to do it. He
6 hasn't answered my question.

7 THE COURT: Well, go ahead.

8 THE WITNESS: I don't -- yes, Your Honor.

9 I don't know because I haven't read this in a long
10 time. So, I could read it and get an idea of what it says,
11 but --

12 BY MR. SCHMIDT:

13 **Q.** All right. Let's do that. Let's go to the bottom of
14 this page, please. And if you look at the very bottom, you
15 can see it says Section 1306.12, very bottom, is revised to
16 read as follows. And then it has on Page 8 the text of the
17 language. Do you see that? Do you see that, sir?

18 **A.** Yes. I'm looking at it right now.

19 **Q.** And then, on Page 8, it has the new language of the
20 rule. Do you see that?

21 **A.** Yes.

22 **Q.** There's no limit on pills in that new language,
23 correct?

24 **A.** No. I believe there is a limit.

25 **Q.** Where does that appear?

1 **A.** If you're looking for a 90-day supply, it's based on
2 the instructions. That's why it says a 90-day supply. So,
3 if the instructions are one tablet every -- every six hours,
4 that would be 120 tablets. So, you would get 120 tablets
5 per prescription.

6 **Q.** Is there any limit here placed on the number of tablets
7 that could be provided pursuant to an individual
8 prescription up to 90 days?

9 **A.** Again, it is my view and the way I looked at it was
10 that 90-day supply was -- pertains to the amount in the
11 prescription based on the instructions in the prescription.

12 **Q.** Did it --

13 MR. ACKERMAN: Your Honor, I feel like we've asked
14 the same question and gotten the same answer now six or
15 seven times and I -- if Mr. Schmidt doesn't like the answer,
16 I'm sorry, but that's clearly this witness's understanding.

17 MR. SCHMIDT: That's true that I've asked the same
18 question and gotten the same answer. Not one of them has
19 been responsive. But I'll move on. I think the record
20 stands as it is and the witness is refusing to answer.

21 MR. ACKERMAN: Move to strike that last comment.

22 BY MR. SCHMIDT:

23 **Q.** Let's go to Page 6. We saw on Page 7 that it talked
24 about people in support of this change, correct?

25 **A.** I'm sorry. Could you repeat that?

1 **Q.** We saw on Page 7, the language we were looking at, that
2 this regulation or this rule making talked about people who
3 supported this change. Do you remember we read that
4 language into the record?

5 **A.** Yes.

6 **Q.** There were also people who opposed it, correct?

7 **A.** Yes. I'm sure there were. There were always people
8 that opposed that.

9 **Q.** Let's look at that. Third paragraph from the bottom.
10 It says appropriateness of this rule in view of the extent
11 of prescription controlled substance abuse in the United
12 States. Do you see that?

13 **A.** Yes.

14 **Q.** And some of the commentators who objected to the
15 proposed rule, among those, quote, "many pointed to the
16 alarming increase in prescription controlled substance abuse
17 in the United States and resulting deaths and harm to the
18 public welfare." Those were comments you received opposing
19 this lengthening of the time that doctors could give
20 prescription opioids for without seeing their patients,
21 correct?

22 **A.** Yes.

23 **Q.** And then, if we go a little further up, it says
24 possibility of increased pressure on prescribing
25 practitioners and it talks about some commentators and the

1 second line at the end asserting practitioners might feel
2 undue pressure to prescribe a 90-day supply of controlled
3 substances at each office visit. Do you see that?

4 **A.** Yes.

5 **Q.** And this rule change was made at a time you were
6 grappling with internet pharmacies, right?

7 **A.** Yes.

8 **Q.** This rule change was made at a time that you started to
9 see a problem with rogue pain clinics, correct?

10 **A.** There were pain clinics out there at the time, yes.

11 **Q.** And just -- quick point on rogue pain clinics. Did you
12 ever adopt a rule or a practice where you refused to
13 register doctors if they were in pain clinics?

14 **A.** No.

15 **Q.** Why not?

16 **A.** Because there are pain clinics that are actually not
17 rogue.

18 **Q.** Okay. Did you ever refuse to register pharmacies that
19 dispensed prescriptions to doctors working at pain clinics?

20 **A.** Refuse or take action against?

21 **Q.** Refuse?

22 **A.** On an application, you're talking about?

23 **Q.** Yes, sir.

24 **A.** Well, I wouldn't know if they were taking pain clinic
25 patients unless they were actually registered to be

1 pharmacies.

2 **Q.** That's with I'm taking about. The ones that are
3 registered as pharmacies, did you ever condition their
4 registration on them not supplying -- filling prescriptions
5 from doctors at pain clinics?

6 **A.** Any pharmacy registration is conditioned on the fact
7 that if you do fill prescriptions outside the usual course
8 of professional practice and not for legitimate medical
9 purpose and corresponding responsibility they could have
10 their license removed.

11 **Q.** I'm asking a little bit of a different question, sir.
12 Did you ever make a rule that you would not register them if
13 they filled prescriptions from any pain clinic?

14 **A.** Of course not.

15 **Q.** For the same reason you just told me about, right?

16 **A.** Yes.

17 **Q.** Now, you touched on a topic I wanted to ask you about.
18 You agree with me that the most common, most frequent method
19 of obtaining a pharmaceutical controlled substance for
20 non-medical use is through friends and family for free?

21 **A.** No. I -- repeat that question again. I want to make
22 sure I got that one right.

23 **Q.** Sure. Of course. The most frequent method of
24 obtaining a pharmaceutical controlled substance for
25 non-medical use is friends and family for free?

1 **A.** Yes. I've testified to that based on the opinion of
2 the Administration, but that was not my own personal view.

3 **Q.** You've also given presentations on that point, haven't
4 you?

5 **A.** That's right. That's the Administration's position.

6 **Q.** Did you espouse any views when you were at the
7 Administration that you believed to be false or untrue?

8 **A.** What -- to who, to the Administration?

9 **Q.** No, to Congress in the presentations you made on behalf
10 of the Administration?

11 **A.** I always presented the information that the
12 Administration approved and that was based on a survey.
13 That was based on a survey that I didn't necessarily agree
14 with, but it was their position, so I was the government
15 vehicle to get their message to Congress.

16 **Q.** Do you mind answering my question now, please?

17 **A.** Yes.

18 **Q.** In doing that, did you ever express views you believed
19 to be false?

20 **A.** I -- yeah. I presented views that I didn't agree with
21 but, I don't know if they're false or not. It was my
22 opinion. I didn't agree with them, but --

23 **Q.** Okay. Well, I don't want to ask you about opinions, so
24 I'm going to focus on truth and not truth. These views --
25 when you expressed the view that the most frequent method of

1 obtaining a pharmaceutical controlled substance for
2 non-medical use is friends and family for free, did you
3 believe that was a false view?

4 **A.** I didn't express that view. Again, again, that is the
5 view of the Administration. When I testified before
6 Congress, I'm not testifying as Joe Rannazzisi. I'm
7 testifying as the Administration. When I'm going before any
8 kind of public meeting, I'm -- I'm presenting as the
9 Administration, not Joe Rannazzisi.

10 **Q.** Let me come back to my question. When you testified
11 before Congress that the most frequent method of obtaining a
12 pharmaceutical controlled substance for non-medical use was
13 friends and family for free, did you believe that to be a
14 false statement?

15 **A.** No.

16 MR. ACKERMAN: Objection, Your Honor. Asked and
17 answered.

18 THE COURT: Overruled. You may answer.

19 THE WITNESS: In my opinion, I did not agree with
20 that. I did not agree with that statement. Do I know it's
21 false? No. I don't know it's false, but I did not agree
22 with that statement.

23 BY MR. SCHMIDT:

24 **Q.** Did you ever tell Congress I don't agree with this but
25 this is the DEA position?

1 **A.** That's -- that's not how congressional testimony works.
2 Congressional testimony, you're presenting for the
3 Administration for the Department of Justice.

4 **Q.** Is the answer to my question no, you never did?

5 **A.** No, I never did.

6 MR. SCHMIDT: May I approach, Your Honor?

7 THE COURT: Yes.

8 BY MR. SCHMIDT:

9 **Q.** I have some excerpts of a 2013 presentation with your
10 name on it. Do you see that on the cover slide regarding
11 drug trends?

12 **A.** Yes.

13 **Q.** This is excerpts. If you go to Page 2 of the document
14 --

15 MR. ACKERMAN: Objection, Your Honor. The problem
16 we have is that defendants don't disclose their documents to
17 us beforehand, so I don't know what's omitted from this
18 document. So, I can't really object to it without finding
19 it among a massive stack.

20 So, I would object to questioning regarding a portion
21 of a document that, if we can work out the excerpts before
22 the questioning, I think that's a different story. But to
23 just present a witness with a self-selected cherry-picked
24 excerpt of a document is improper.

25 MR. SCHMIDT: It's for impeachment, Your Honor.

1 THE COURT: Yeah, overruled.

2 BY MR. SCHMIDT:

3 Q. Do you see on Page 2 in this presentation you gave it
4 says most frequent method of obtaining a pharmaceutical
5 controlled substance for non-medical use, friends and family
6 for free? Do you see that?

7 A. Yes.

8 Q. And do you know if you gave that -- made that statement
9 at presentations more than once?

10 A. Yes. That was the Government's position.

11 Q. At any of those presentations did you say this is the
12 Government's position, but my opinion, I disagree with it?

13 A. I wouldn't do that. That's not what we're allowed to
14 do.

15 Q. Did you believe you were saying something false when
16 you said this?

17 A. No. I -- as I said before, I didn't agree with it, but
18 they had a survey to back it up, so I didn't have a choice
19 but to go with it.

20 Q. Do you have any contrary data?

21 A. Yeah, our investigations.

22 Q. I mean like a study or a survey?

23 A. No. Just our investigations.

24 Q. And then the next slide says medicine cabinet and then
25 problem, pharmaceutical controlled substance disposal. Do

1 you see that?

2 **A.** Yes.

3 **Q.** And then it says so many drugs in the household, why,
4 and then it gives two reasons. Do you see that?

5 **A.** Yes.

6 **Q.** One is unreasonable quantities being prescribed. Do
7 you see that?

8 **A.** Yes.

9 **Q.** And that refers to decisions being made by doctors,
10 correct?

11 **A.** Yes.

12 **Q.** And do you believe that to be true, that some of the
13 contributions to unreasonable levels of drugs in the
14 household is unreasonable quantities being prescribed?

15 **A.** Yes.

16 **Q.** And just to be clear, what I understand you to be
17 talking about here is that if -- and I think you touched on
18 it in the context of that 90-day rule, that if you have a
19 lot of opioids given to a given patient, someone else might
20 use them?

21 **A.** Yes.

22 **Q.** Someone might take them. They might steal them. They
23 might give them away. And that can be -- that is diversion?

24 **A.** Well, technically, yes.

25 **Q.** Every one of those is diversion, right, stealing,

1 giving away, selling?

2 **A.** Well, if it's in the patient's hands, once it's in the
3 patient's hands, if it's stolen, it's just -- it's stolen.
4 It's not necessarily diversion.

5 **Q.** Okay, fair enough.

6 **A.** Because the patient is not within the closed system of
7 distribution.

8 **Q.** And that form of diversion or theft can occur even if a
9 distributor, or a pharmacy, or a manufacturer does what
10 they're supposed to do, right? They could fill a good faith
11 prescription written for an unreasonable quantity, or even a
12 reasonable quantity, and some could be stolen, given away,
13 sold?

14 **A.** What did you say initially? Just -- I didn't hear the
15 first part of the question.

16 **Q.** The first part of my question was you can have a
17 prescription written in good faith where, as to that
18 prescription, the doctor does what they're supposed to do,
19 the pharmacy does what they're supposed to do, the
20 distributor does what they're supposed to do, and the
21 manufacturer does what they're supposed to do, and it still
22 gets sold, stolen or given away?

23 **A.** Yes.

24 **Q.** The second point you have on this slide is insurance
25 rules. Do you see that?

1 **A.** Yes.

2 **Q.** What are you referencing there?

3 **A.** Some insurance companies require a 90-day supply,
4 60-day supply, depending on the insurance company for
5 filling, but not necessarily controlled substances.

6 **Q.** And, actually, one more question about this document.
7 I apologize. I want to make sure I just have this.

8 When you told Congress and others that the most
9 frequent method of obtaining a pharmaceutical controlled
10 substance for non-medical use was friends and family for
11 free, you understood that to be the position of the DEA,
12 correct?

13 **A.** It was the position of the Administration so, yes.

14 **Q.** In making public statements about prescription opioids,
15 there were occasions where you would refer doctors to
16 standards adopted by their State Medical Boards, correct?

17 **A.** We always refer the doctors to their State Medical
18 Boards because only the states dictate the practice of
19 medicine.

20 **Q.** In fact, you took the position that the DEA encourages
21 physicians to seek guidance from the State Medical Boards,
22 correct?

23 **A.** Again, yes. The states dictate the practice of
24 medicine. So, yes, that's been said before.

25 MR. SCHMIDT: And I didn't ask to approach. I'm

1 sorry, Your Honor.

2 BY MR. SCHMIDT:

3 **Q.** Do you recognize Exhibit P-9270 as an article that you
4 wrote that was published in June of 2000 in a publication
5 called Clinical Pharmacology and Therapeutics? My question,
6 sir, simply is do you recognize this article as an article
7 you have written?

8 **A.** I wrote a lot of articles. My name is on it, so I'm
9 sure I wrote it, but I just don't recall this one.

10 MR. SCHMIDT: We'd move into evidence Exhibit
11 P-09270.

12 MR. ACKERMAN: Can I have a minute to consult with
13 my colleagues, Your Honor?

14 THE COURT: I'm sorry?

15 MR. ACKERMAN: I just need to minute to consult
16 with my colleagues.

17 THE COURT: Yes. Yes.

18 MR. SCHMIDT: And if I can just ask one question
19 while you're consulting, just for the record.

20 BY MR. SCHMIDT:

21 **Q.** If you look at the bottom, do you see under your name
22 it says -- it's not just any J. T. Rannazzisi. It's J. T.
23 Rannazzisi from the Office of Diversion Control Drug
24 Enforcement Administration, Alexandria, Virginia. Do you
25 see that?

1 **A.** Yes.

2 **Q.** And there's a DEA -- I guess it's an e-mail address
3 where you --

4 MS. SINGER: Excuse me, Mr. Schmidt. Could you
5 just give us one minute before you ask the question?

6 MR. SCHMIDT: Yes. Sure. Of course.

7 MS. SINGER: Thank you.

8 (Pause)

9 MR. ACKERMAN: So, Your Honor, we have no
10 objection to introducing medical literature provided that we
11 are afforded the same courtesy.

12 MR. SCHMIDT: I don't see how --

13 THE COURT: That depends entirely on what the
14 medical literature is, Mr. Ackerman.

15 MR. ACKERMAN: I understand. We have no objection
16 to this document.

17 MR. SCHMIDT: Okay.

18 THE COURT: You want it admitted, Mr. Schmidt?

19 MR. SCHMIDT: Yes, please, Your Honor.

20 THE COURT: All right. It's admitted.

21 BY MR. SCHMIDT:

22 **Q.** All right. So, let's just look at that language that I
23 was reading you. It was on the right-hand side. Do you see
24 where you wrote in this article, this is a pharmacology and
25 therapeutics article, that the DEA encourages physicians to

1 seek guidance from their State Medical Boards? That's that
2 proposition we've been discussing, correct?

3 **A.** Yes. We've gone over that in the past, yes.

4 **Q.** And that's something you did throughout your career at
5 DEA, correct?

6 **A.** When speaking to physicians groups, yes.

7 **Q.** Let's look at an example of that.

8 MR. SCHMIDT: Your Honor will recall that we used
9 a book earlier and I believe Mr. Hester promised we would
10 give the Court a hard copy of the book, so I want to carry
11 through on that promise, if I may.

12 THE COURT: Yes. I would like to have some more
13 things up here.

14 MR. SCHMIDT: This one is slender. It's MCWV-2111
15 and it's in evidence.

16 And then there's paper copies if anyone wants a paper
17 copy of the pages.

18 BY MR. SCHMIDT:

19 **Q.** There's been testimony in this case that this book was
20 sent by the Medical Boards of 13 states, including West
21 Virginia, to every doctor in those 13 states, including West
22 Virginia. Is that something that you were aware of when you
23 told doctors to look to the guidance they received from
24 State Medical Boards?

25 **A.** I know this book has been used in certain areas of the

1 country. I didn't know that the Medical Boards were sending
2 the books to all the doctors.

3 **Q.** Okay. But you knew it was being used?

4 **A.** This book?

5 **Q.** Yes.

6 **A.** This book has been around for awhile, yes, sir.

7 **Q.** And I didn't give you a hard copy. I apologize for
8 that. Do you want my copy or do you want a paper copy? I
9 can give you just --

10 **A.** A paper copy is fine.

11 **Q.** Okay.

12 THE COURT: He can have mine, Mr. Schmidt.

13 MR. SCHMIDT: We desperately want Your Honor to
14 have it.

15 BY MR. SCHMIDT:

16 **Q.** All right. Let's just look at a couple of pages of
17 this. If we go to Page 9 of the book, which is Document
18 Page 15, do you see in the upper right corner there's some
19 bullets? Tell me when you're there, sir.

20 **A.** I'm on Page 15.

21 **Q.** You see the first bullet says patients should not be
22 denied opioid medication except in light of clear evidence
23 that such patients [sic] are harmful -- such medications are
24 harmful to the patients? Do you see that language?

25 **A.** Yes.

1 **Q.** Were you aware at the time you referred doctors to
2 State Medical Boards that statements like this were being
3 sent by Medical Boards to doctors in at least 13 states?

4 MR. FARRELL: Objection, Your Honor. I think that
5 misstates the testimony.

6 THE COURT: Overruled.

7 BY MR. SCHMIDT:

8 **Q.** Were you aware of that, sir?

9 **A.** No. Like I said, I wasn't aware that this book was
10 being passed out by the Medical Boards.

11 **Q.** Okay. Go to Page 94 of the book. Do you see where
12 there's a heading Federal Guidelines For Prescribing
13 Controlled Substances? Do you see that heading?

14 **A.** Yes.

15 **Q.** And do you see -- if you just kind of scroll through
16 there, do you see reference to the 2006 policy statement
17 that you spent some time talking about earlier today?

18 **A.** Yes.

19 **Q.** And then if we continue on to the next page, Page 95,
20 do you see that there's -- this came out before the 90-day
21 rule we were just talking about was finalized, but do you
22 see there's discussion of that rule being proposed?

23 **A.** Okay.

24 **Q.** Now, you said -- I'm not going to go through the rest
25 of this book. I'm going to wrap up just with a couple of

1 questions.

2 When you were at DEA, you said you knew about this
3 book. Did you ever -- you or your colleagues at DEA ever
4 issue any kind of statement correcting anything you believed
5 to be wrong in this book?

6 **A.** No. DEA did not get involved in medical practice.

7 **Q.** Do you see on the cover it says Federation of State
8 Medical Boards?

9 **A.** Yes.

10 **Q.** On multiple occasions you've relied on guidelines from
11 the Federation of State Medical Boards, correct?

12 **A.** Yes.

13 **Q.** And, in fact, one of those occasions is actually
14 referring to distributors to the Federation of State Medical
15 Boards, correct?

16 **A.** I'd have to see it.

17 **Q.** All right.

18 **A.** Referring to the internet pharmacy? I don't -- I would
19 have to see what you're referring to.

20 **Q.** Fair enough. Let me help you out. Let's pull up
21 P-1205, which is in evidence. I think it is a document you
22 were shown, so you should have it in your stack, and it is
23 the distributor slides. And let's go to Page 9 of that
24 document.

25 And do you see that there is reference to -- in giving

1 guidance to distributors, there's reference to the
2 Federation of State Medical Boards as something distributors
3 can look to in understanding medical need?

4 **A.** Okay.

5 **Q.** That's guidance you gave to distributors about
6 understanding medical need, correct?

7 **A.** Yeah. Because we're talking about the model guidelines
8 of internet, yes.

9 **Q.** I want to touch very quickly on the other participants
10 in the closed system starting with pharmacies. Pharmacies
11 are also required to have a DEA registration, correct?

12 **A.** Yes.

13 **Q.** They're also required to renew it periodically?

14 **A.** Yes.

15 **Q.** Why is that?

16 **A.** Again, every three years so we can do background and
17 make sure that they are indeed licensed appropriately and
18 have not had any disciplinary action.

19 **Q.** Are you aware of any instance from your work at DEA
20 where any one of the three distributors in this case
21 supplied controlled substances to a Huntington or Cabell
22 County pharmacy that was not registered with the DEA?

23 **A.** No.

24 **Q.** Are you aware of any instances from your tenure at DEA
25 where one of the defendants supplied prescription opioids to

1 a DEA licensed pharmacy in Huntington or Cabell that the DEA
2 had warned the distributor not to supply?

3 **A.** Not that I'm aware of.

4 **Q.** You talked for a bit yesterday about whether
5 distributors should require certain information from
6 pharmacies or not do business with them. Do you remember
7 that?

8 **A.** Yes.

9 **Q.** Have you ever made it a condition for registration of
10 pharmacies that in order to be registered they had to give
11 distributors certain categories of information?

12 **A.** No.

13 **Q.** For example, did you ever say if you're going to be
14 registered as a pharmacy, you've got to share dispensing
15 data or doctor information with distributors?

16 **A.** No, we didn't tell them that.

17 **Q.** Did you ever tell distributors as a condition of
18 registration that they had to get that kind of data from
19 every pharmacy or refuse to do business with them?

20 **A.** No. That would be part of their due diligence. That's
21 up to them.

22 **Q.** Let's talk about manufacturers. DEA must also register
23 manufacturers for them to be able to make controlled
24 substances, correct?

25 **A.** Yes.

1 **Q.** Manufacturers are the ones responsible for studying the
2 safety and the benefits of prescription opioids and other
3 medications that they make, correct?

4 **A.** Yes.

5 **Q.** And they're the ones who obtain FDA approval for new
6 prescription opioids, correct?

7 **A.** Yes.

8 **Q.** And I'm not going to ask you too much about the FDA,
9 but do you have an understanding that at least when it came
10 to prescription opioids, the FDA was only supposed to
11 approve a prescription opioid if they determine that the
12 benefits outweigh its known and potential risks for the
13 intended population?

14 MR. ACKERMAN: Objection to scope, Your Honor.
15 This is --

16 THE COURT: Overruled.

17 BY MR. SCHMIDT:

18 **Q.** Do you want me to re-ask it?

19 **A.** The FDA's approval process is on safety and efficacy.

20 **Q.** And they've got to determine that the safety -- that
21 the benefits outweigh the risks, right?

22 **A.** I believe that's built into it, safety and efficacy,
23 yes.

24 **Q.** Are you aware that the physician warnings that
25 manufacturers were required to provide for the prescription

1 opioids warned doctors that they had a risk of abuse and
2 addiction?

3 **A.** In the literature? I'm sure it's in there, yes.

4 **Q.** Are you aware of any distributor in this case that
5 distributed opioids in Huntington or Cabell that were not
6 approved by the FDA?

7 **A.** I'm not aware of any.

8 **Q.** Are you aware of an instance where the DEA ever told a
9 distributor in this case not to do business with the DEA
10 registered manufacturer?

11 **A.** I -- I don't have any information on that.

12 **Q.** Okay. Let me ask you just a few more questions on
13 distributors and then I'll turn to a different topic.

14 Distributors aren't authorized to write prescriptions,
15 correct?

16 **A.** That's correct.

17 **Q.** They don't evaluate a patient's legitimate medical need
18 for opioids in terms of deciding whether the opioids are
19 appropriate for that patient, correct?

20 **A.** That's correct.

21 **Q.** They can't second-guess legitimate medical decisions by
22 prescribers, correct?

23 **A.** I don't understand when they would be questioning a
24 legitimate medical prescription.

25 **Q.** And they don't have access to individual patient

1 medical records because of privacy laws, correct?

2 **A.** They wouldn't have access to that.

3 **Q.** There's been discussion in this case about a term "know
4 your customer's customer". That's not a term you were
5 familiar with during your time with DEA, correct?

6 **A.** No. "Know Your Customer", not "Know Your Customer's
7 Customer".

8 **Q.** You recognize that distributors play an important role
9 in insuring an adequate and uninterrupted supply of
10 prescription opioids?

11 **A.** Yes.

12 **Q.** It's important -- it's an important role in terms of
13 them being able to move those drugs downstream and ensure
14 that pharmacies and hospitals have those drugs, correct?

15 **A.** Yes.

16 **Q.** And that's important because if a patient doesn't get
17 the medication they need, there's a breakdown in the system,
18 correct?

19 **A.** Yes.

20 **Q.** And that role is a similar role, or a similar interest,
21 a similar purpose, to the DEA in ensuring an adequate
22 supply, correct? Distributors are part of that process of
23 ensuring an adequate supply?

24 **A.** Yes.

25 **Q.** You agree that it's critical for patients who have a

1 medical need for prescription opioids to have access to
2 them?

3 **A.** Yes.

4 **Q.** A couple small points. During your ten years at DEA,
5 you never told distributors to retain due diligence files on
6 all of their customers for all time, correct?

7 **A.** I personally did not, no.

8 **Q.** You can't identify anyone at DEA who told that to
9 distributors, correct?

10 **A.** No. It's just common sense that if they're doing due
11 diligence and they're maintaining files, they would maintain
12 files for the duration of that customer's business
13 relationship so they could see and reach back and look at
14 what the prescribing patterns were from the beginning all
15 the way up to the present.

16 **Q.** While you were at DEA you recognized that ARCOS data
17 was helpful to the agency in generating leads for
18 investigations, correct?

19 **A.** Yes.

20 **Q.** Registrants requested ARCOS data from DEA, but DEA
21 declined to share it, correct?

22 **A.** Yes. We were -- we were instructed that we could not
23 share it, yes.

24 **Q.** Do you know that DEA has not been required to give
25 distributors limited access to ARCOS?

1 **A.** I do from the deposition, the last deposition, yes.

2 **Q.** Did you ever support giving distributors more access to
3 ARCOS than they were allowed or the access that they enjoy
4 today?

5 **A.** It wasn't a question of whether I supported it or not.
6 It's a question of what I was allowed to do during my tenure
7 and the answer is no.

8 **Q.** Did you ever take steps to try to grant greater access?

9 **A.** Again, we're getting into internal deliberate process
10 about what we can and can't do.

11 **Q.** All I'm asking you, sir, is if you took any such steps.
12 I don't want to hear about discussions with people.

13 **A.** We --

14 **Q.** I want to know -- let me finish, please. I just want
15 to know if you took any steps to try to grant greater access
16 to ARCOS data when you were at DEA?

17 MS. SINGER: Objection, Your Honor. I think this
18 is the same issue that defendants were raising yesterday if
19 we can't probe on redirect the reasons for any decision
20 making that leads to an unbalanced and unfair situation
21 where they illicit testimony that can't be fully explored.

22 THE COURT: Well, the question was if he took any
23 steps to try and grant greater access to ARCOS. I'm going
24 to let him answer that question.

25 THE WITNESS: I personally did not take any steps.

1 BY MR. SCHMIDT:

2 Q. I'm going to close out with one topic. I want to talk
3 about some of those DEA powers that you talked about in your
4 direct examination. And I want to actually put something in
5 front of you and ask you about it, if I can, because it will
6 frame some of my questions a little more easily.

7 MR. SCHMIDT: May I approach, Your Honor?

8 THE COURT: Yes.

9 MR. SCHMIDT: For the record, this is MCWV-1081.
10 It's testimony from July, 2006 before the Subcommittee on
11 the House of Representatives. Do you see that?

12 A. Yes.

13 Q. And if you go to Page 61 -- I'm sorry -- actually, 63
14 in the lower corner. Wait. 65, I'm sorry. 65 in the lower
15 left corner. Do you see that?

16 A. That's Page 65.

17 Q. Do you see your prepared statement?

18 A. Yes.

19 Q. All right. I'd like to look at Page 72, please, in the
20 lower left corner within your prepared statement. And
21 here's what I would like to ask you about, sir.

22 A. Okay.

23 Q. It says in the third full paragraph, do you see where
24 it says the CSA, the Controlled Substances Act, includes
25 seven major controlled mechanisms? Do you see that?

1 **A.** Yes.

2 **Q.** And then it lists them. Do you see that?

3 **A.** Yes.

4 **Q.** And is that an accurate list of different control
5 mechanisms that the CSA grants the DEA?

6 **A.** No. That -- that seems to be accurate.

7 **Q.** Okay. First one is scheduling. That's Schedule II,
8 III, IV, et cetera?

9 **A.** Yes.

10 **Q.** And the second one is registration, correct?

11 **A.** Yes.

12 **Q.** And that's registration of all the participants in the
13 closed system, correct?

14 **A.** Yes.

15 **Q.** I'm going to skip a couple. The last one is
16 investigational authority, correct?

17 **A.** Yes.

18 **Q.** And then if you go to actually the third one, it's
19 quotas, correct?

20 **A.** Yes.

21 **Q.** And then you talked yesterday and we talked a little
22 bit today about your power to enact regulations when
23 appropriate, correct?

24 **A.** Yes.

25 **Q.** And you can also give guidance, correct?

1 **A.** Yes.

2 **Q.** All right. I want to ask you about those four points,
3 please. Before I leave this document, if we look at the
4 next sentence, these mechanisms allow DEA to monitor and
5 regulate a controlled substance and its movement. Do you
6 see that?

7 **A.** Yes.

8 **Q.** Is that true?

9 **A.** Yes.

10 **Q.** In the case of the most potentially dangerous drugs in
11 Schedule II, we register all persons who handle them. We
12 inspect the documentation of their distribution. We control
13 their import and export. And we control the amount
14 produced, bought, sold, and otherwise transferred. Do you
15 see that?

16 **A.** Yes.

17 **Q.** And all of that is true, correct?

18 **A.** Yes.

19 **Q.** So, let's go through those categories very quickly.

20 **A.** Okay.

21 **Q.** First, registration. And I can show you that there's
22 -- this information. Are you aware that the DEA website
23 tracks the number of registered pharmacies, registered
24 practitioners, over time?

25 **A.** I've seen slides to that effect, but I haven't seen

1 them in awhile, so --

2 **Q.** Do you take any issue with the fact that the number of
3 DEA registrations issued to pharmacies in West Virginia went
4 up by about a hundred between -- or 20 percent between 2005
5 and 2015? Do you take any issue with that?

6 **A.** I wouldn't know.

7 **Q.** Okay. Well, let me show you then.

8 MR. SCHMIDT: And may I approach, Your Honor? Two
9 single page documents.

10 BY MR. SCHMIDT:

11 **Q.** Mr. Rannazzisi, Exhibit MCWV-2183 is a printout from
12 the Diversion Control Division Registration -- Registrant
13 Population by State and Business. Do you see that?

14 **A.** Yes.

15 **Q.** And it allows you to select a state that that box that
16 says West Virginia and it allows you to select a time
17 period. It looks like we actually chose later, August --
18 August, 2006. Do you see that?

19 **A.** Yes.

20 **Q.** And there's 513 DEA registered pharmacies. Do you see
21 that?

22 **A.** Yes.

23 **Q.** And 5,446 DEA registered practitioners. Do you see
24 that?

25 **A.** Yes.

1 **Q.** If you go to the next slide, or the next document,
2 MCWV-2197, it's the same web page, also for West Virginia,
3 this time for October, 2015. And do you see that the
4 pharmacies have gone from 513 to 600, nearly a hundred?

5 **A.** Okay.

6 **Q.** And that practitioners have gone from 5,446 to 6,656,
7 more than a thousand? Do you see that?

8 **A.** Yes.

9 MR. SCHMIDT: We'd move these two into evidence,
10 Your Honor.

11 THE COURT: Any objection?

12 MR. ACKERMAN: No objection.

13 THE COURT: They're both admitted.

14 BY MR. SCHMIDT:

15 **Q.** My question on this to you simply is I take it your
16 judgment at DEA was that that increase in both pharmacy and
17 doctor registrations both by somewhere in the order of
18 20 percent was appropriate given medical needs and
19 legitimacy of those pharmacies --

20 THE COURT: Let me interrupt and ask you a
21 question. What's a mid-level practitioner on that chart?

22 THE WITNESS: Your Honor, that would be a
23 physician's assistant, advanced practice nurse, and certain
24 -- podiatrists.

25 THE COURT: And they're authorized under some

1 circumstances to prescribe opioids?

2 THE WITNESS: Yes, sir. The way -- the way that
3 the Controlled Substances Act works is we look to the State.
4 If the State grants them the ability to prescribe controlled
5 substances, we're required -- unless they have some kind of
6 felony in their background, we're required to give them a
7 license.

8 BY MR. SCHMIDT:

9 Q. And just to complete the record, that category for
10 mid-level practitioners, more than doubled from 910 to
11 2,023, correct?

12 A. Yes.

13 Q. I take it you had view that this growth in
14 registrations from mid-level practitioners, practitioners
15 and pharmacies was appropriate?

16 A. Well, the State dictates the practice of medicine, the
17 practice of pharmacy, and the oversight of the mid-level.
18 So it's what the state believes is appropriate, not what DEA
19 believes.

20 Q. Well, in terms of DEA granting them a separate
21 registration, did DEA believe it was appropriate to
22 separately register them under its standards?

23 A. As long as they met the appropriate licensure
24 requirements under the State, DEA has really no choice but
25 to -- to register them.

1 **Q.** I want to focus on -- we -- you and I talked earlier
2 about the .01 percent of the doctors that DEA takes action
3 against on an annual basis. Yesterday you were asked about
4 16,000 doctors. Do you remember that testimony?

5 **A.** Yeah. I think it was a range, but --

6 **Q.** Yeah. You agree that it's a good thing to require DEA
7 criminal background investigations of all new registrant
8 applications, correct?

9 **A.** There should be a background investigation done, yes.

10 **Q.** There was a period of time where you didn't do any
11 background checks either with the initial registration of a
12 prescriber or subsequent registration of a prescriber,
13 correct?

14 **A.** There was a time where we -- there was a time where we
15 were not given access to certain databases and we had to go
16 through private -- private means to get that background
17 information, yes.

18 **Q.** Well, I think that's a little different than what I
19 asked. Let me try one more time.

20 Did there come a point in time where you didn't do any
21 background checks either with the initial registration of a
22 prescriber or a subsequent registration of a prescriber?
23 Yes or no, if you can?

24 **A.** I don't recall. I -- I know there was a time where
25 there was an issue with that. I just don't recall the exact

1 time and the length of that time.

2 **Q.** Can we cull up the July 16th, 2020 transcript at Page
3 129, Lines 2 through 7?

4 **MR. ACKERMAN:** For the record, Your Honor, we'd
5 renew our objection to use of this transcript, which is not
6 the MDL transcript.

7 **THE COURT:** All right. Overruled.

8 **BY MR. SCHMIDT:**

9 **Q.** Question, then there came a point in time where you
10 didn't do any background checks, either with initial
11 registration of a prescriber or subsequent registration of a
12 prescriber, correct? And your answer was no. We relied on
13 the State. Did I read that correctly?

14 **A.** Yes. And I said we relied on the State, but there were
15 other things that occurred, but that's -- that's absolutely
16 correct. We did rely on the State.

17 **Q.** And you're aware of government findings from after your
18 watch that you relied on the good faith of applicants to
19 disclose relevant information, correct?

20 **A.** Yes.

21 **Q.** And that's a true statement, that you relied on the
22 good faith of applicants to disclose relevant information,
23 correct?

24 **A.** And the State, yes.

25 **Q.** Do you know with specificity what types of background

1 checks West Virginia did?

2 **A.** I don't know.

3 **Q.** Let me ask you, does prescriber registration from the
4 DEA, in your view, provide meaningful protection to the
5 public against improper prescribers?

6 **A.** Yes.

7 **Q.** Let's go to the second category, investigations. Do
8 you know there are times where distributors told the DEA
9 they were cutting off pharmacies, correct?

10 **A.** I'm sorry. Can you repeat, please?

11 **Q.** Of course. Do you know there are times, occasions,
12 when distributors told the DEA that they were cutting off
13 pharmacies, correct?

14 **A.** Yes.

15 **Q.** And of the instances where that happens, you don't know
16 what percentage of those pharmacies DEA actually
17 investigated, correct?

18 **A.** No. As I sit here, no.

19 **Q.** You can't tell me if it was 10 percent, 50 percent, 1
20 percent, correct?

21 **A.** I don't know.

22 **Q.** You can't tell me what percentage of the tens of
23 thousands of suspicious orders that DEA received on your
24 watch that actually directly led to an investigation,
25 correct?

1 **A.** I don't -- I don't know and I don't think I could -- I
2 don't think I could tell you that even if I did know.

3 **Q.** Okay. I'll stand on your you don't know. Do you know
4 whether it was more than one percent of suspicious orders
5 reported that resulted in an investigation? Do you know?

6 **A.** I don't know.

7 **Q.** Okay. Can you identify any suspicious orders reported
8 for pharmacies in Huntington or Cabell? And I don't want
9 you to tell me which ones, but can you any that resulted in
10 investigations?

11 **A.** I don't know.

12 **Q.** You're aware that DEA has been criticized for its use
13 of Suspicious Order Reports that have been submitted by
14 distributors, correct?

15 **A.** Could you repeat that, please?

16 **Q.** Are you aware that DEA has been criticized by the
17 Office of the Inspector General for its use of suspicious
18 orders submitted by distributors?

19 **A.** Can you tell me which report you're referring to? Is
20 that the 2019 report?

21 THE COURT: Just a minute.

22 Mr. Ackerman?

23 MR. ACKERMAN: Actually, let the witness clarify
24 first because I think that will explain my objection.

25 THE COURT: All right.

1 THE WITNESS: 2019 report?

2 MR. SCHMIDT: Yes.

3 MR. ACKERMAN: All right. So, Your Honor, counsel
4 is now beginning to question regarding a 2019 Office of the
5 Inspector General Report. That report was issued after the
6 MDL deposition. It was not addressed in the MDL deposition.
7 So, we'd offer our scope objection consistent with your
8 ruling on the permissible scope of Mr. Rannazzisi's
9 testimony with respect to this line of questioning.

10 MR. SCHMIDT: It relates to his tenure, sir.

11 THE COURT: Pardon me?

12 MR. SCHMIDT: It relates to his tenure, Your
13 Honor.

14 THE COURT: Yes. Overruled. This is cross
15 examination. I'm going to allow it.

16 By MR. SCHMIDT:

17 **Q.** Are you aware of that 2019 report that takes issue with
18 how DEA dealt with Suspicious Order Reports on your watch?

19 **A.** I remember there was a section in there about
20 suspicious orders, yes.

21 **Q.** And one of the findings from that report, do you
22 recall, is that DEA Field Division staff did not receive
23 access to the Suspicious Order Reporting System until 2017,
24 after your tenure; do you recall that?

25 **A.** No. I -- if you can --

1 **Q.** Of course.

2 **A.** I would like to read that.

3 MR. SCHMIDT: May I approach, Your Honor?

4 THE COURT: Yes.

5 MR. SCHMIDT: This is in evidence.

6 MR. FARRELL: Judge, on behalf of Cabell County
7 and to save us some time, does this open the door for
8 re-direct on this document with this witness?

9 THE COURT: Well, we'll cross that bridge when we
10 get to it, Mr. Farrell.

11 MR. FARRELL: Thank you.

12 BY MR. SCHMIDT:

13 **Q.** And do you recognize this document as the one we've
14 been discussing?

15 **A.** Yes.

16 **Q.** And if you look on Page 36, it says in the middle
17 paragraph five lines, six lines, seven lines down, one
18 diversion program manager.

19 MR. SCHMIDT: Can you highlight that language from
20 the middle paragraph, please?

21 BY MR. SCHMIDT:

22 **Q.** Described the SORS database as a "joke", noting that
23 DEA Field Division staff did not receive access to the SORS
24 database until 2017, nearly ten years after it was created.
25 Are you aware of that finding?

1 **A.** I'm sorry. Which page are we on here?

2 **Q.** It's little numbered Page 36.

3 **A.** 36?

4 **Q.** In the lower left. Were you aware of that finding,
5 sir?

6 **A.** Yes. That was from one diversion investigator, one
7 diversion program manager, who said that.

8 **Q.** Your understanding is that when there was follow-up on
9 Suspicious Order Reports it would be done by the local Field
10 Office agents, correct?

11 **A.** Yes.

12 **Q.** Are you aware of any suspicious orders -- well, I think
13 I probably asked this.

14 Let's move to the next category. And I'm actually
15 going to jump to number 4, regulations and guidance.

16 Could we cull out P-34, which is a copy of your 2007
17 letter? And I'm just going to point you to specific
18 language. If we go to the second paragraph of your letter
19 and the second last sentence. Accordingly, DEA does not
20 approve -- wrong sentence. The one before, please.

21 Accordingly, DEA does not approve or otherwise endorse
22 any specific system for reporting suspicious orders. Do you
23 see that?

24 **A.** Yes.

25 **Q.** That was your view throughout your tenure at DEA,

1 correct?

2 **A.** Yes.

3 **Q.** Are you aware of any of your predecessors stating that
4 view in writing in a document you could point us to?

5 **A.** I -- I don't -- I can't recall if there was or was not.

6 **Q.** Now, let me focus on your watch, 2005 to 2015. I
7 believe you've covered this, but I need to make sure I've
8 covered it. On your watch you made clear that how a
9 distributor created a Suspicious Order Monitoring System was
10 for them to figure out, correct?

11 **A.** They were required to create their own system, yes.

12 **Q.** You refused to approve individual suspicious order
13 monitoring systems, correct?

14 **A.** We weren't authorized to approve suspicious order
15 monitoring systems.

16 **Q.** While you were at the DEA you took the position that it
17 was up to the distributors to figure out whether an
18 individual order was suspicious or not, right?

19 **A.** It was up to the distributor to determine what's
20 suspicious and what's not.

21 **Q.** You took the position that it was up to the distributor
22 to figure out whether to ship an order or not, correct?

23 **A.** That's correct.

24 **Q.** And you took the position that it's up to the
25 distributor to figure out whether to increase thresholds for

1 individual pharmacies, correct?

2 **A.** We never talked about thresholds with the distributors.
3 It's not -- it was the position of the Drug Enforcement
4 Administration. All of these things that you just mentioned
5 were the Drug Enforcement Administration's position.

6 **Q.** That they had figure out their own thresholds, correct?

7 **A.** Yes.

8 **Q.** You never told distributors that if you take specific
9 steps in your diligence programs, that would be compliant,
10 correct?

11 **A.** I don't follow your question.

12 **Q.** Did you ever say to distributors if you take these
13 specific steps in your diligence, that will be compliance?

14 **A.** No.

15 **Q.** You never told distributors that if you used these
16 criteria to try to assess suspicious orders and anytime you
17 see an order that triggers these criteria and you report it
18 to the DEA, you will be meeting your suspicious order
19 reporting obligations, correct?

20 **A.** I don't recall saying that.

21 **Q.** And I think you touched on this yesterday. You had a
22 policy of not sharing with distributors when you were
23 investigating a pharmacy customer of theirs, correct?

24 **A.** We're not authorized to share investigative
25 information.

1 **Q.** And I think you said due process concerns for the
2 pharmacy, correct?

3 **A.** Due process, but also internal Justice Department. We
4 can't confirm an investigation.

5 **Q.** So, if a distributor asked one of your agents should we
6 be worried about this pharmacy we're supplying and you were
7 conducting an investigation of that pharmacy let's say for
8 something horrible like exchanging drugs for sex, that would
9 not be disclosed to the distributor, correct, under this
10 policy you've referenced?

11 **A.** We would have to seek guidance from the U. S. Attorney
12 or the Department of Justice.

13 **Q.** Absent getting that guidance, you would not share that
14 information, correct?

15 **A.** That's -- that's correct.

16 **Q.** And you understand that DEA investigations of doctors
17 and pharmacies can, in some instances, take years and years
18 and years?

19 **A.** That's correct.

20 **Q.** And the time you mentioned in your examination, the one
21 time you mentioned where you learned that one of your agents
22 was doing that, was sharing a list of, hey, watch out for
23 these pharmacies, you told that agency to stop that,
24 correct?

25 **A.** Well, didn't say watch out for these pharmacies.

1 That's not what was in the e-mail. The e-mail basically
2 listed pharmacies and said these pharmacies were cut off by
3 another distributor.

4 **Q.** The one time that happened you told that agent to stop,
5 correct? You stopped that practice, correct?

6 **A.** That's correct.

7 **Q.** It was commonplace for distributors like McKesson, and
8 ABDC, and Cardinal to come in and give briefings to the DEA,
9 correct, about their programs?

10 **A.** I don't know if it's commonplace, but I know they come
11 in.

12 **Q.** Well, let me ask it this way. Is it true that
13 registrants come in and give briefings to the DEA all the
14 time?

15 **A.** Registrants.

16 **Q.** Okay. And that has included occasions where the
17 defendants in this case come in and give briefings, correct?

18 **A.** Yes. Defendants have been at the headquarters, yes.

19 **Q.** We talked about some of the presentations in 2008.
20 After that point in time, you're aware that distributors
21 continued to ask for guidance from DEA?

22 **A.** I was aware later on that they did, but it was through
23 liaison policy, which is normal. That's what normally
24 happens.

25 **Q.** For example, you know that in June of 2011,

1 distributors sent DEA a letter asking for guidance on
2 suspicious order monitoring and reporting through their
3 Trade Association?

4 **A.** Yes.

5 **Q.** And DEA did not answer that letter, correct?

6 **A.** That's correct. We were directed not to answer that
7 letter.

8 **Q.** Distributors sent another letter asking for guidance
9 two years later, in July of 2013, regarding things like
10 diligence and suspicious order reporting through their Trade
11 Association, correct?

12 **A.** That's correct.

13 **Q.** And, again, they actually did that in connection with a
14 planned meeting with DEA, correct?

15 **A.** I don't know about that, but they did send that letter
16 and, again, we were directed not to answer that letter.

17 **Q.** Are you aware that the DEA cancelled the meeting and
18 ignored the letter?

19 **A.** Well, we were directed not to answer the letter and I'm
20 sure the meeting was cancelled. If there was a meeting,
21 then I'm sure it was cancelled.

22 **Q.** Do registrants have a right to expect responses to
23 written, electronic or telephonic requests from the DEA?

24 MR. ACKERMAN: Objection.

25 THE COURT: What's the objection?

1 MR. ACKERMAN: Foundation, argumentative, outside
2 the scope.

3 MR. SCHMIDT: One of the road map stops was
4 guidance, Your Honor, and I'm -- I'll lay a foundation.

5 MR. ACKERMAN: But the question wasn't about DEA's
6 guidance. It was about whether respondents have -- about
7 respondents' expectations.

8 THE COURT: Yes. The question was do registrants
9 have a right to expect a response. You have to lay a
10 foundation for that one, Mr. Schmidt.

11 BY MR. SCHMIDT:

12 **Q.** Do you understand that the DEA believed that DEA
13 registrants have a right to expect responses to written
14 electronic or telephonic requests?

15 **A.** DEA registrants, yes, they have a right, but not
16 advocacy groups.

17 **Q.** Do you have an understanding that DEA registrants have
18 a right to expect guidance regarding the CSA and its
19 regulations?

20 **A.** Yes, but again, the individual registrants can come in
21 and request that guidance. The advocacy group doesn't
22 really represent all of the distributors.

23 **Q.** You're aware that government watchdogs made findings
24 that DEA should give more guidance to distributors while you
25 were at DEA, correct?

1 **A.** Yes.

2 MR. SCHMIDT: May I approach, Your Honor?

3 THE COURT: Yes.

4 BY MR. SCHMIDT:

5 **Q.** I've given you a report from the GAO, June, 2015. More
6 DEA Information About Registrants' Controlled Substances
7 Roles Could Improve Their Understanding and Help Ensure
8 Access, DEF-WV-2181. This report came out on your watch,
9 correct?

10 **A.** Yes.

11 **Q.** And you're aware of this report, correct?

12 **A.** Yes. I wrote the response to it.

13 **Q.** And I was just going to point that out. If we look at
14 Page 82, you actually wrote a response to a draft of it,
15 correct?

16 **A.** Yes.

17 **Q.** Let's go to Page 82, please. I'm sorry, page 89. And
18 there we see your response, correct?

19 **A.** Yes.

20 **Q.** All right. Let's look at Page 34 of this report. And
21 I'm using the number in the lower left corner again. This
22 is shortly before you left DEA, correct?

23 **A.** Yeah. About three or four months before.

24 **Q.** They state a guidance document for distributors -- I'm
25 looking in the first full paragraph. A guidance document

1 for distributors similar to the one offered for pharmacies
2 and practitioners could help distributors further understand
3 and meet their roles and responsibilities under the CSA for
4 preventing diversion, though the document may not need to be
5 as detailed. Did I read that correctly?

6 **A.** Yes.

7 **Q.** Were you aware of that finding?

8 **A.** When I read that, yes, I was.

9 **Q.** Okay. If we skip a sentence, they give an example.
10 They say DEA could -- it's actually two lines up and I
11 didn't skip a sentence. I started halfway through the
12 sentence because there's a comma where it looks like there
13 would be a period or something. DEA could, for example,
14 provide guidance around best practices in developing
15 suspicious order monitoring systems. Were you aware of that
16 finding?

17 **A.** Yes.

18 **Q.** DEA could also enhance its proactive communications
19 with distributors. And then they give some examples. Do
20 you see that?

21 **A.** Yes.

22 **Q.** And then let's skip to the next sentence. Such steps
23 are key to addressing distributors' concerns, as without
24 sufficient guidances and communication from DEA,
25 distributors may not be fully understanding or meeting their

1 roles and responsibilities under the CSA for preventing
2 diversion. Do you see that?

3 **A.** Can I read that one more time?

4 **Q.** Of course.

5 **A.** Thank you.

6 Yes. I see that.

7 **Q.** And then they say, additionally, in the absence of
8 clear guidance from DEA, our survey data show that many
9 distributors are setting thresholds on the amount of certain
10 controlled substances that can be ordered by the customers,
11 I.e., pharmacies and practitioners, which can negatively
12 impact pharmacies and ultimately patients' access. Do you
13 see that?

14 **A.** Yes.

15 **Q.** Do you agree with the idea that if thresholds are set
16 too low they can negatively impact pharmacies and ultimately
17 patient access?

18 **A.** Well, I -- I can't agree or disagree because I don't
19 know how you're setting the threshold and I don't know the
20 customer. I don't know where the customer sits. So, no, I
21 can't agree or disagree.

22 **Q.** Fair. Let's go to their recommendations on Page 51.
23 Do you see that they have three recommendations for
24 executive action? The second is solicit input from
25 distributors or associations representing distributors.

1 That would be a group like HDMA, correct?

2 **A.** Had, yes.

3 **Q.** What you referred to as an advocacy organization?

4 **A.** That's what it is.

5 **Q.** And develop additional guidance for distributors,
6 regarding their roles and responsibilities for suspicious
7 orders monitoring and reporting. Do you see that?

8 **A.** Yes.

9 **Q.** I take it -- well, let me -- let me ask you one more
10 question.

11 MR. SCHMIDT: May I approach, Your Honor?

12 THE COURT: Yes.

13 BY MR. SCHMIDT:

14 **Q.** Mr. Rannazzisi, I've put in front of you MCWV-2208. Do
15 you see that? It's dated December 20th, 2016, U. S.
16 Department of Justice. And if you look at the Bates number
17 in the bottom corner, you can see that this was provided to
18 us by the DEA. Do you see this document?

19 **A.** Yes.

20 MR. SCHMIDT: I'd move this into evidence, Your
21 Honor.

22 THE COURT: Any objection?

23 THE WITNESS: No. Have I seen this document?

24 MR. SCHMIDT: No. I said do you see this
25 document?

1 THE WITNESS: Oh, do I see it? Okay.

2 MR. SCHMIDT: I'm about to ask you that question
3 but, first, I want to move it into evidence.

4 MR. ACKERMAN: I don't think he's laid the
5 foundation because the only question was do you see this
6 document.

7 MR. SCHMIDT: It's a U. S. Department of Justice
8 letter to the Government Accountability Office produced by
9 the DEA in this litigation. I think it's a government
10 record.

11 THE COURT: Mr. Farrell?

12 MR. FARRELL: Yeah. I don't believe this is --
13 I'm not saying he can't get the foundation to it, but I
14 don't think he's laid it.

15 MR. SCHMIDT: I'm trying to -- I'm trying to
16 short-circuit, but let me see if I can help.

17 BY MR. SCHMIDT:

18 **Q.** Do you see it relates to in the subject line Re: DEA
19 Status Reports? And then it references that GAO Report you
20 were just looking at. Do you see that?

21 **A.** Yes.

22 **Q.** And do you see it's written to the Director of
23 Healthcare and the Government Accountability Office, the
24 Office of the Government that wrote that report we were just
25 looking at?

1 **A.** Yes.

2 **Q.** And do you see in the first line it says the Drug
3 Enforcement Administration provides the following status
4 reports on actions taken to address the GAO Report? Do you
5 see that?

6 **A.** Yes.

7 MR. ACKERMAN: Your Honor --

8 MR. SCHMIDT: We'd move it in as a government
9 record, Your Honor.

10 MR. ACKERMAN: So, Your Honor, this is after his
11 tenure at the DEA. There's no -- Mr. Rannazzisi hasn't
12 testified to anything other than the contents of a document
13 that counsel hasn't established he saw before sitting on the
14 stand today. All that he testified to was that the document
15 says what's on its face.

16 MR. SCHMIDT: And, Your Honor, what I think is
17 appropriate is for me to be able to move this in as a
18 business record, as a government record, and then I will ask
19 Mr. Rannazzisi if he's seen it. If he hasn't, I'll move on,
20 but I think it's important to --

21 THE COURT: Have you laid the basis for it as a
22 government record as an exception to the hearsay rule?

23 MR. SCHMIDT: I believe we have, Your Honor.
24 Under Rule 806 -- I'm sorry. Under Rule 803 --

25 MR. FARRELL: Judge, to save you some time, our

1 objection is premised upon maintaining the scope of Mr.
2 Rannazzisi as a fact witness and if the defendants believe
3 that documents produced by the DEA are self-authenticating
4 and admissible, we agree, and note that there are many such
5 attached to the Prevosnik deposition.

6 MR. SCHMIDT: Your Honor, I have not looked at
7 those documents. I move this document in. And I'm moving
8 it in under 803 --

9 THE COURT: (8).

10 MR. SCHMIDT: 803(8), yes. Thank you. It sets
11 out the Office's activities. It sets out a matter observed
12 while under a legal duty to report. And it's factual
13 findings from a legally authorized investigation insofar as
14 this is the DEA responding to a GAO investigation with their
15 update on steps taken as a result of that. It's all three
16 clauses.

17 MR. ACKERMAN: The problem here, Your Honor, is
18 that that's Mr. Schmidt's testimony. There's no testimony
19 from a witness as to -- as to what this is. So, it's
20 different from the documents that Mr. Rannazzisi saw during
21 his tenure at the DEA and can testify to. There's not a --
22 there's not a foundation from a witness.

23 MR. SCHMIDT: And I'll note, too, I believe the
24 plaintiffs have given us designations for DEA witnesses and
25 includes this as an exhibit. So, I think we can stipulate

1 that it comes in. You want it for Mr. Strait (phonetic).
2 We want it for -- for the record. And then, I'll ask Mr.
3 Rannazzisi if he knows about it. If he doesn't, I'll move
4 on.

5 MR. ACKERMAN: I'm looking at the people who know
6 more about this than I do.

7 THE COURT: I'm going to sustain the objection to
8 this one on the basis of a lack of proper foundation through
9 this witness.

10 MR. SCHMIDT: May I just ask him if he's seen it
11 before?

12 THE COURT: You can use it to ask him some
13 questions and --

14 MR. SCHMIDT: Okay.

15 BY MR. SCHMIDT:

16 Q. Let's go to the second page. Do you see it repeats the
17 finding at the top regarding soliciting input from
18 distributors or associations representing distributors, that
19 language we looked at?

20 MR. ACKERMAN: Your Honor, it's your discretion,
21 but I'd note that the document is still on the screen as if
22 it's been admitted. Now it's not.

23 THE COURT: It's been removed. Okay.

24 MR. SCHMIDT: It's gone.

25 BY MR. SCHMIDT:

1 Q. Do you see that finding we talked about?

2 MR. FARRELL: Objection, Your Honor. I don't know
3 that he's identified that the witness has seen this
4 document, let alone seen Page 2.

5 MR. SCHMIDT: I'm trying to move it in. Your
6 Honor just said I could ask him -- use it as a basis to
7 cross-examine and --

8 THE COURT: Well, yeah. You can use it as a basis
9 to ask him questions --

10 MR. SCHMIDT: Okay.

11 BY MR. SCHMIDT:

12 Q. Do you see that finding --

13 THE COURT: -- for cross examination.

14 BY MR. SCHMIDT:

15 Q. Do you see that finding we've just discussed, sir?

16 A. On number 2?

17 Q. Yes, at the top of Page 2?

18 A. Okay.

19 Q. And then, if you look at the second paragraph, do you
20 see it says the GAO survey was conducted in 2015, prior to
21 new DEA leadership, including a new acting administrator and
22 new management for the Diversion Control Division.

23 MR. FARRELL: Objection, Your Honor.

24 THE COURT: Mr. Farrell?

25 MR. FARRELL: He's simply reading it into the

1 record now rather than asking him questions.

2 THE COURT: Sustained.

3 MR. SCHMIDT: My question was simply going to be
4 did he know about it and --

5 THE COURT: Well, you can ask him the question,
6 but don't --

7 BY MR. SCHMIDT:

8 Q. Did you know about that finding?

9 A. No, I did not.

10 Q. Do you know about Congressional testimony Chuck
11 Rosenberg gave before Congress after you left about the DEA
12 being opaque when providing guidance to distributors?

13 A. I heard that before, yes.

14 Q. Are you aware that he said "I think we've been slow. I
15 think we've been opaque. I think we haven't responded to
16 them"?

17 A. I'm aware of that. I don't know where he got that
18 information from. He never received a briefing from me
19 before I left.

20 Q. Last topic, quotas. DEA sets quotas for controlled
21 substances each year, correct?

22 A. Yes.

23 Q. But based on the estimated medical scientific research
24 and industrial needs of the United States, correct?

25 A. That's correct.

1 **Q.** And they're designed to set an exact quantity that will
2 meet the legitimate medical demands, yet won't be more than
3 necessary that could be removed to the illicit marketplace,
4 correct?

5 **A.** It's an estimate. It's not an exact quantity.

6 **Q.** But that's the estimate, correct?

7 **A.** That's the estimate.

8 **Q.** And distributors can only ship pills that manufacturers
9 make within the quota, correct?

10 **A.** That's correct.

11 **Q.** You said you oversaw the aggregate production quota,
12 the APQ, correct?

13 **A.** Yes. My staff did that.

14 **Q.** And I just want to go back to that earlier OIG Report.

15 **A.** Yes.

16 **Q.** DEF-WV-1597. And the reason I'm going to this is
17 because it has a helpful chart that shows quota changes over
18 time. It's at Page 19 of the document, please.

19 **A.** Yes.

20 **Q.** And are you generally familiar with the quota changes
21 that happened at least on your watch between, according to
22 this, 2015 and 2005? I probably did a terrible job at
23 drawing those lines. I put my 2015 a little farther over.
24 But are you generally familiar with those quota increases?

25 **A.** Yes.

1 Q. During your tenure?

2 A. Yes.

3 Q. And they had -- to be fair to you, they had started
4 increasing before your tenure, going all the way back into
5 the late 90s, correct?

6 A. Yes.

7 Q. And they continued to increase during your tenure,
8 correct?

9 A. Uh-huh, yes.

10 Q. And am I correct in understanding from your testimony
11 yesterday that you believe that those increases were driven
12 by good faith prescribing practices?

13 A. I think my testimony was prescribing practices and then
14 research and development, export, and the other things, yes.

15 Q. Okay. And the prescribing practices portion of that
16 was driven by legitimate medical need, correct?

17 A. Well, legitimate medical need and then, of course,
18 doctors that are prescribing illegally.

19 Q. Okay. You said yesterday you took diversion into
20 account though in setting the quota, correct?

21 A. We looked at that over the years, yes.

22 Q. And you had the concern that if you arbitrarily cut the
23 level of the quota, that could have negative consequences
24 for real-life patients, correct?

25 A. Yes, that's correct.

1 Q. Now --

2 THE COURT: If you're at a stopping place, Mr.
3 Schmidt, we need to take a break.

4 MR. SCHMIDT: Okay. Why don't we take a break,
5 Your Honor.

6 THE COURT: Is this is a good place?

7 MR. SCHMIDT: Yes, sir.

8 THE COURT: All right. Let's be in recess for
9 about ten minutes.

10 (Recess taken)

11 (Proceedings resumed at 3:40 p.m. as follows:)

12 THE COURT: Mr. Schmidt.

13 MR. SCHMIDT: Thank you.

14 BY MR. SCHMIDT:

15 Q. Mr. Rannazzisi, I have one final topic that I hope
16 is brief that I have to cover in light of some of the
17 opinions you've given. You gave some pretty strong
18 opinions about the distributors in this case. Correct?
19 You offered -- let me re-ask. You offered some pretty
20 strong views on the distributors in this case; correct?

21 A. I offered views on distributors, yes.

22 Q. You've also offered strong views in your work on
23 doctors in terms of blaming doctors; correct?

24 A. I've discussed doctors and what their role is, yes.

25 Q. For example, just a few weeks ago you recorded on a

1 television showing saying the opioid crisis started with
2 prescriptions, prescriptions and patient care, this idea
3 that we weren't adequately treating pain. Correct?

4 **A.** Which show was that?

5 **Q.** It was the HBO show.

6 **A.** I don't have a transcript, but I seem to remember
7 saying something about doctors during that time.

8 **Q.** Do you believe that the opioid crisis started with
9 prescriptions?

10 **A.** I believe the opioid crisis -- the prescriptions had a
11 lot to do with the opioid crisis, yes.

12 **Q.** Do you believe it started with prescriptions?

13 **A.** I would say that prescriptions -- yes, I'd say that.

14 MR. SINGER: Objection, move to strike, Your
15 Honor. I think Mr. Schmidt, after objecting to expert
16 opinions from this witness, is now seeking just that.

17 THE COURT: Well, I don't think that's an expert
18 opinion. That's a lay opinion based on his experience,
19 isn't it, Mr. Schmidt?

20 MR. SCHMIDT: I think so, Your Honor.

21 THE COURT: I'll overrule the objection.

22 BY MR. SCHMIDT:

23 **Q.** You've taken issue with manufacturers in your work;
24 correct?

25 **A.** Yes.

1 Q. You've taken issue with chain pharmacies in your work;
2 correct?

3 A. Yes.

4 Q. You blamed independent pharmacies; correct?

5 A. Yes.

6 Q. In terms of you, you had ultimate authority of the
7 Office of Diversion Control for 10 years during the opioid
8 crisis; correct?

9 A. Yes.

10 Q. There was an opioid crisis the entire time that you
11 were the head of DEA's Office of Diversion Control; correct?

12 A. That's correct, yes.

13 Q. It worsened during your tenure; correct?

14 A. It, it did increase, yes.

15 Q. Including here in West Virginia; correct?

16 A. I -- yes.

17 Q. And you were the senior --

18 A. Across the country.

19 Q. Yes. You were the senior most law enforcement official
20 at DEA responsible for pharmaceutical diversion; correct?

21 A. That's correct, yes.

22 Q. And despite the issue you've taken with others, am I
23 right that you take no responsibility for the opioid crisis?

24 A. I don't take any responsibility for the opioid crisis,
25 no.

1 Q. Zero percent?

2 A. Yes, zero percent.

3 Q. In fact, I've had the chance to ask you questions about
4 your fulfillment of these responsibilities, and you've told
5 me when it comes to registration, with the powers available
6 to you, you believe you were perfect?

7 A. We did registration in line with what the law allowed
8 us to do, yes.

9 Q. Registration of doctors and pharmacies, given the
10 powers you had, did you execute those powers perfectly?

11 A. We executed them according to the law. So if we're
12 dealing with the law, yes, we, we did it as far as the law
13 would allow us to do.

14 Q. Given the powers you had to investigate doctors and
15 pharmacies, you exercised those perfectly. True?

16 A. Yes, within the resources we had and within the law, we
17 did, yes.

18 Q. Given the powers you had regarding quotas, you believe
19 you executed those powers perfectly; correct?

20 A. Again, we were required to follow the statutes and the
21 laws related to quota and we did so appropriately, yes.

22 Q. You believe you did so perfectly given the powers you
23 had regarding quotas?

24 A. We did the best we could do within the confines of the
25 law, yes.

1 **Q.** Let's cull up July -- all right. Nevermind. And you
2 think you gave perfect guidance to distributors; correct?

3 **A.** We gave the distributors the guidance that we were able
4 to give within the confines of the policies and procedures
5 of both DEA and DOJ.

6 **Q.** And you wouldn't do anything differently in terms of
7 how you approached the opioid crisis while you were at the
8 DEA; correct?

9 **A.** I've thought about this because you asked that before.

10 **Q.** Do you remember how you answered it before?

11 **A.** I wasn't, I wasn't sure. I wasn't -- I don't remember
12 how I answered it before, but I, I didn't have a lot of time
13 to think about it.

14 **Q.** Okay. Would you do things differently? Just "yes" or
15 "no"?

16 **A.** It's not a "yes" or "no" question.

17 **Q.** I'll move on then. You left the DEA in 2015; is that
18 right?

19 **A.** Yes.

20 **Q.** And, in your words, you retired because they
21 transferred you to another area of the DEA and you felt it
22 was time to leave; correct?

23 **A.** Yes. They, they transferred me -- they basically said
24 that I'll be in a position that will be named later so --

25 **Q.** You went from supervising 300 people to supervising no

1 people; correct?

2 **A.** That's correct.

3 **Q.** And that wasn't a change you wanted; correct?

4 **A.** I accept the fact that the acting administrator -- you
5 serve at the will of the administrator. And the acting
6 administrator wanted to make a change, so I accepted that
7 fact.

8 **Q.** It wasn't a change you requested, was it?

9 **A.** It wasn't a change that I requested, no.

10 **Q.** And instead of agreeing to hold a position where you
11 supervised no people, you chose to retire; correct?

12 **A.** I decided that there was uncertainty with what was
13 going to happen. I could have been transferred. I didn't
14 want my family to get transferred another time. So I
15 decided to stay -- to retire, yes.

16 **Q.** At the time you retired, or prior to the time you
17 retired, the Office of the Inspector General opened an
18 investigation of you regarding serious misconduct with the
19 House of Representatives; correct?

20 **A.** They opened an investigation of me because the House of
21 Representatives -- two, two representatives claimed that I
22 tried to intimidate them.

23 **Q.** And you left the DEA without getting a letter from the
24 Office of Inspector General exonerating you; correct?

25 **A.** I never received a letter.

1 Q. Since you've left, you now get a government pension;
2 correct?

3 A. I do have a government pension, yes.

4 Q. And your only other income comes from working with
5 plaintiff lawyers; correct?

6 A. Yes.

7 Q. And I think you said the other day, or maybe yesterday,
8 that you've received \$860,000 for working with plaintiff
9 lawyers in opioid litigation since you left the DEA;
10 correct?

11 A. Yes, since 2017.

12 Q. And you testified that you weren't getting paid for
13 your testimony here; correct?

14 A. Testimony or prep.

15 COURT REPORTER: I'm sorry?

16 THE WITNESS: Prep, testimony or preparation.

17 BY MR. SCHMIDT:

18 Q. But you have been paid money, a small portion of
19 that \$860,000 from one of the law firms in this case;
20 correct?

21 A. Yes, a very small portion.

22 Q. Small portion being \$7,000; correct?

23 A. Yes.

24 MR. SCHMIDT: That's all I have, Your Honor.

25 THE COURT: Any other cross of Mr. Rannazzisi?

1 MS. WICHT: Yes, Your Honor, there will be. Can I
2 just have the Court's indulgence for a moment while we get
3 set up here?

4 THE COURT: Yes.

5 MS. WICHT: Thank you.

6 CROSS EXAMINATION

7 BY MS. WICHT:

8 **Q.** Good afternoon, Mr. Rannazzisi.

9 **A.** Good afternoon.

10 **Q.** My name is Jennifer Wicht and I represent Cardinal
11 Health. I am going to be doing my best to not duplicate any
12 of the questions, or many of the questions you've already
13 answered so far. And as a result, it may seem that I'm
14 jumping around a little bit among topics. So I apologize
15 for that and I hope you can follow me.

16 So I want to start, Mr. Rannazzisi, by following up
17 on -- just a little bit on the questions that you addressed
18 both with Ms. Singer and with Mr. Schmidt and you testified
19 about pain clinics. Do you recall generally testifying
20 about that topic?

21 **A.** Yes.

22 **Q.** Okay. And I, I believe the testimony that you've
23 already given is that there are pain clinics that are
24 legitimate -- engaged in the legitimate practice of
25 medicine; correct?

1 **A.** That's correct.

2 **Q.** And there are also prescribers who specialize in the
3 treatment of pain; correct?

4 **A.** That's correct.

5 **Q.** And the same thing that's true of pain clinics is true
6 of prescribers who specialize in the practice of pain; that
7 is, there are prescribers who specialize in the practice of
8 pain who are engaged in the legitimate practice of medicine.
9 Correct?

10 **A.** That's correct.

11 **Q.** So not -- just because a doctor is a pain specialist
12 doesn't mean that they're prescribing in any sort of a rogue
13 fashion; correct?

14 **A.** Could you repeat that, please?

15 **Q.** Sure. Just because a physician is a pain specialist,
16 that doesn't mean that they're prescribing in any sort of a
17 rogue fashion?

18 **A.** That's correct. In the alternative, a pain specialist
19 can prescribe in a rogue fashion as well.

20 **Q.** But not all of them are?

21 **A.** That's correct, not all of them.

22 **Q.** Okay. I want to just go back for a moment to the
23 definition of suspicious orders in the Code of Federal
24 Regulations. And I think we have our own version of it that
25 I'll put up on the screen which I think is slide 3, but

1 you've looked at it with both Ms. Singer and Mr. Schmidt.

2 I actually had the wrong slide. I apologize. Can we
3 try 2? There we go.

4 And this -- you recognize that as the Code of Federal
5 Regulations' definition of a suspicious order; correct?

6 **A.** Yes.

7 **Q.** And the Code of Federal Regulations is what provides
8 the legal definition of a suspicious order; correct?

9 **A.** Yes.

10 **Q.** And that's DEA's official definition of a suspicious
11 order as well; right?

12 **A.** The DEA follows the Code of Federal Regulations, yes.

13 **Q.** And there's no other definition that you're aware of of
14 a suspicious order; correct?

15 **A.** Just the Code of Federal Regulations' definition.

16 **Q.** Now, the definition includes some terms we've already
17 talked about; orders of unusual size, orders deviating
18 substantially from a normal pattern, and orders of unusual
19 frequency. Correct? Those are the components of the
20 definition of a suspicious order under the regs?

21 **A.** Yes.

22 **Q.** And the regs don't -- the regulations do not further
23 define the term "unusual size;" correct?

24 **A.** That's correct.

25 **Q.** Nor do they offer a further definition of "unusual

1 frequency;" right?

2 **A.** That's correct.

3 **Q.** And they don't define what it means to deviate
4 substantially from a normal pattern; correct?

5 **A.** That is correct.

6 **Q.** And the regulation doesn't quantify what the line is
7 between usual and unusual; right?

8 **A.** That is correct also.

9 **Q.** And, now, when you were at DEA -- and I'll talk about
10 your time between 2005 and 2015 that we've generally been
11 focused on -- if a registrant asked you what a suspicious
12 order was, you would tell them it's an order of unusual
13 size, frequency, or substantially deviating from a normal
14 ordering pattern; correct?

15 **A.** We would refer them to the regs. And if they had a
16 specific question, then depending on who they were talking
17 to, if it was liaison policy, I'm sure the liaison policy
18 would have given them some type of guidance if it's specific
19 to, specific set of facts.

20 **Q.** You would have referred the registrant to the
21 definition in the, in the regulation; correct?

22 **A.** Unless they had some specific set of facts that they
23 were looking for, yes.

24 **Q.** And if a registrant had a specific set of facts about
25 an order, would the DEA tell them that's an order of unusual

1 size or pattern or frequency?

2 **A.** No. I'm talking about a specific set of facts as far
3 as -- for instance, if they'd say, "What if I have a
4 customer that's ordering an over-abundance of a certain type
5 of drug?" And then I believe that they might say, "Well,
6 what's the drug?" And they might say, "Well, we would
7 consider this in the category of substantially deviating,"
8 say. So they might -- further explain. And then actually
9 the letter, the December, 2007 letter further explained
10 those as well.

11 **Q.** During your tenure, sir, isn't it correct that DEA took
12 the position that it would not tell a registrant whether a
13 particular order was a suspicious order under the definition
14 of the regs?

15 **A.** That's correct. We would not be specific -- we would
16 not tell a registrant, "This is, this is suspicious, don't
17 ship it." We wouldn't say that.

18 **Q.** And it's true, is it not, that in your view there are
19 lots of different ways that you could define unusual size;
20 right?

21 **A.** Yes.

22 **Q.** It could mean unusual in comparison to that particular
23 pharmacy's past ordering practices; right?

24 **A.** That's correct.

25 **Q.** It could mean unusual when compared to the ordering

1 practices of other pharmacies in the area; correct?

2 **A.** That's also correct.

3 **Q.** And there could be other factors that would bear on
4 whether an order was of unusual size as well; correct?

5 **A.** Yes.

6 **Q.** And, now, the word "unusual" also applies to the
7 consideration of order frequency under the regulations;
8 correct?

9 **A.** Yes.

10 **Q.** And those various definitions or ways of determining
11 whether an order is unusual are not spelled out in the
12 regulations; correct?

13 **A.** No.

14 **Q.** And let me -- you, you testified about the possibility
15 that if a registrant called, your staff might provide
16 guidance or input to the registrants on a particular
17 situation they had.

18 So let me just ask you this. You're not aware, are
19 you, Mr. Rannazzisi, of any specific guidance that your
20 staff offered to a registrant; correct?

21 **A.** No. However, that's -- the December letter provided a
22 little more specific guidance on what an unusual -- what to
23 look for on unusual size, frequency, deviating substantially
24 from the normal ordering pattern.

25 **Q.** Since you mentioned the December of 2007 letter, let me

1 just ask -- that was the last guidance letter that your
2 office sent to registrants, correct, during your tenure at
3 DEA?

4 **A.** Yes.

5 **Q.** There were no additional letters sent after that
6 providing guidance?

7 **A.** I don't recall any additional letters.

8 **Q.** You've testified, Mr. Rannazzisi, on direct examination
9 about -- that distributors in their Suspicious Order
10 Monitoring Systems could use dispensing data from their
11 pharmacy customers. Do you recall that?

12 **A.** Yes.

13 **Q.** And, and that's a subject that you've offered opinions
14 about in a, in a different opioid case, correct, dispensing
15 data and suspicious order monitoring?

16 **A.** I don't recall if I discussed that in the MDL
17 deposition or another case. I know I discussed it. I just
18 don't remember which case I discussed it in.

19 **Q.** Okay. No problem. And I want to be -- I really was
20 only saying that to say that I want to be clear. I'm not
21 asking for any opinions that you may have offered somewhere
22 else.

23 **A.** Okay.

24 **Q.** What I want to ask you is while you were at the DEA,
25 Mr. Rannazzisi, you never told distributors that they must

1 or should be collecting dispensing data from their pharmacy
2 customers and incorporating it into their Suspicious Order
3 Monitoring Systems; correct?

4 **A.** I never told anybody --

5 **Q.** And --

6 **A.** -- that.

7 **Q.** And --

8 **A.** But that doesn't -- you know, that doesn't include the
9 staff. That was one of the things that I'm sure they
10 discussed with the distributors.

11 **Q.** You're not aware of any instance in which staff
12 discussed that with any distributor; correct?

13 **A.** I can't give you a specific instance, but I knew staff
14 knew the dispensing data was important.

15 **Q.** And while you were at the DEA, DEA, to your knowledge,
16 never issued any written guidance telling distributors that
17 they must or should collect dispensing data from customers;
18 correct?

19 **A.** I never said they should collect. I've said during due
20 diligence they should review it if they can't resolve the
21 reason for the, for the anomalies and ordering patterns. So
22 we suggest it's part of the due diligence process.

23 **Q.** Well, let's be clear, though. You've testified that
24 you never -- you don't recall ever saying that to any
25 distributor though; correct?

1 **A.** I never said it.

2 **Q.** And you're not aware of staff saying that to any
3 distributor; correct?

4 **A.** I can't give you an instance where staff has said that.

5 **Q.** I'm going to ask you some questions specific to
6 Cardinal Health, Mr. Rannazzisi.

7 Yesterday Ms. Singer refreshed your recollection with
8 an affidavit that you signed in the Cardinal Health, 2012
9 Cardinal Health action. Do you remember that?

10 **A.** Yes. It was a declaration in lieu of testimony.

11 **Q.** Okay. And after she showed you that declaration, you
12 testified that DEA conducted an audit of Cardinal Health's
13 Peabody, Massachusetts distribution center; and that during
14 that audit, Cardinal Health was given guidance by DEA on due
15 diligence for chain drug stores. Do you recall that?

16 **A.** Yes.

17 **Q.** I just have a few questions about that, Mr. Rannazzisi.
18 To be clear, you did not conduct that audit of Cardinal
19 Health's Peabody distribution center; correct?

20 **A.** No. I believe it was Inspector Mike Arpaio that was
21 the lead auditor in that.

22 **Q.** And he conducted that audit --

23 **A.** Yes.

24 **Q.** -- of Cardinal Health? So everything that you know
25 about that meeting between DEA and Cardinal Health at that

1 audit you learned from Mr. Arpaio; correct?

2 **A.** Yes.

3 **Q.** And that includes anything that Mr. Arpaio might have
4 said to Cardinal Health, correct?

5 **A.** Yes.

6 **Q.** And anything that Cardinal Health employees said to
7 Mr. Arpaio; correct?

8 **A.** That's correct.

9 **Q.** You were shown a copy yesterday of a memo memorializing
10 the internet pharmacy briefing that certain DEA officials
11 conducted with Cardinal Health. Do you recall that?

12 **A.** Yes.

13 **Q.** And we can pull that up. It's P-9114.

14 Do you have that in front of you still, Mr. Rannazzisi?

15 **A.** I'm not even looking for it. It's on the screen.

16 **Q.** Okay. It's on the screen. And the subject line of
17 that memo states "Meeting with Cardinal Health, Inc.,
18 Concerning Internet Pharmacies." Correct?

19 **A.** That's correct.

20 **Q.** And you testified that you didn't attend this meeting;
21 right?

22 **A.** I did not attend this meeting.

23 **Q.** And the memo was prepared by Mr. Michael Mapes;
24 correct?

25 **A.** That's correct.

1 Q. And he did attend the meeting; correct?

2 A. I believe he was the principal briefer, yes.

3 Q. Along with Mr. Kyle Wright from the DEA?

4 A. I can't see who's --

5 Q. Yeah. If you look at the --

6 A. That's what I'm looking at now.

7 Q. You know what --

8 A. Yeah. I don't believe Kyle Wright's in here.

9 Q. Okay. Fair enough. And the, the, the way that you
10 learned about the meeting, Mr. Rannazzisi, was from this
11 memo and a briefing; correct?

12 A. This memo came after I was briefed on the meeting.

13 Q. And --

14 A. I was briefed on the meeting after the meeting either
15 that day or the next day. And then I would get the memo
16 following.

17 Q. And the memo that the DEA staff prepared after the
18 meetings were to inform you about what was said at the
19 meeting and what was talked about; correct?

20 A. Actually, it was to memorialize the meeting.

21 Q. To memorialize the meeting?

22 A. Yes.

23 Q. Okay. And you wanted those memos prepared; correct?

24 A. Those memos would be prepared for any meetings we had,
25 so, yes.

1 Q. And I'm sure you expected your staff to make sure that
2 the memos were complete, didn't you?

3 A. Yes.

4 Q. And, of course, the memos needed to be accurate;
5 correct?

6 A. Yes.

7 Q. And these were important meetings and it was important
8 to you to document what had been said to the distributors at
9 the meeting; correct?

10 A. Yes.

11 Q. And if you thought that the staff would have conducted
12 the meeting and you were missing some information that you
13 thought should have been included, you probably would have
14 added it in or asked them to include it; correct?

15 A. If there was something missing that I knew was missing,
16 I would ask them. But since I wasn't at the meeting, I
17 relied on them to accurately report and memorialize the
18 meeting.

19 Q. So if you take a look at this memo, Mr. Rannazzisi, and
20 it's just the one page that you see on the screen there, the
21 memo doesn't contain any discussion of ingredient limit
22 reports, does it?

23 A. No, it doesn't.

24 Q. It doesn't contain any discussion of excessive purchase
25 reports, does it?

1 **A.** No, it doesn't.

2 **Q.** It doesn't contain any discussion of after-the-fact
3 reports of shipments; correct?

4 **A.** No, the memo doesn't contain any of that.

5 **Q.** The memo doesn't reflect any discussion of -- the memo
6 doesn't say that Cardinal Health was told that when they
7 were recording a suspicious order, they were required to say
8 why the order was suspicious; right?

9 **A.** No, that's not in there either.

10 **Q.** And the memo doesn't say that Cardinal Health was told
11 that when they were reporting a suspicious order, they
12 should provide information about the pharmacy; correct?

13 **A.** No, that's not in there. But I do believe that some of
14 that is -- would be attached in the PowerPoint presentation
15 that was given.

16 **Q.** Well, the PowerPoint presentation -- if you have the
17 exhibit in front of you -- it should be there behind it, Mr.
18 Rannazzisi. So I'll invite you to flip through it and let
19 me know if you see something in the PowerPoint presentation
20 that said when a suspicious order is reported, the
21 distributor is required to say why the order is suspicious.

22 **A.** Well, this was -- I don't know if that was in the
23 PowerPoint or not, but some of the other things you asked
24 me --

25 **Q.** Well --

1 **A.** -- were definitely in the PowerPoint.

2 **Q.** Well, that's what I'm asking you about now. So you're
3 saying -- your answer is that's not in the PowerPoint?

4 **A.** I don't have the PowerPoint in front of me, but I
5 don't, I don't remember it being -- I don't recall it being
6 in the PowerPoint. But I have a lot of paper in front of me
7 so -- you don't happen to have it, do you?

8 **Q.** I believe I do. I can hand you another copy. I'm
9 happy to. It's P-9114. Maybe I don't have it.

10 MS. WICHT: I'm sorry, Your Honor. I'll check.

11 May I approach, Your Honor?

12 THE COURT: Yes.

13 BY MS. WICHT:

14 **Q.** And the question that I've asked you, sir, is
15 whether there's anywhere in that memo or PowerPoint
16 presentation that indicates what information Cardinal
17 Health was required to submit to DEA in a suspicious
18 order report.

19 **A.** I don't, I don't see it in the PowerPoint.

20 **Q.** Now, the, the memo, Mr. Rannazzisi, also doesn't say
21 anything about any obligation to document due diligence;
22 correct?

23 **A.** No, it does not.

24 **Q.** Now, are you aware that Kyle Wright testified that he
25 did not tell distributors in these internet pharmacy

1 briefings that there was an obligation to document due
2 diligence?

3 **A.** No, I was not aware of that. I don't know what Kyle
4 Wright's testimony is.

5 **Q.** I'm sorry. The last part?

6 **A.** I don't know what Kyle Wright's testimony is.

7 **Q.** But Kyle Wright --

8 **A.** I don't even know if Kyle Wright was at this meeting.

9 **Q.** But Kyle Wright in general was one of the presenters at
10 the distributor initiative meetings; correct?

11 **A.** Yeah. He was one of several, several people who
12 attended these meetings.

13 **Q.** And you were not; correct?

14 **A.** No, I was not.

15 **Q.** And are you aware that Mr. Mapes testified that if
16 there had been anything else discussed in the meeting with
17 Cardinal Health, he would have included it in his cover
18 memo?

19 **A.** Again, I didn't see Mr. Mapes' testimony, so I don't
20 know.

21 **Q.** But that would be consistent with your expectations for
22 what was included in the memo; correct?

23 **A.** I would expect that Mr. Mapes would do a complete memo
24 including everything else in -- that happened during the
25 meeting.

1 **Q.** Mr. Rannazzisi, do you know which Cardinal Health
2 distribution center shipped medications to
3 Cabell/Huntington, West Virginia.

4 **A.** No, I don't.

5 **Q.** Are you aware that Cardinal Health has a distribution
6 center in Wheeling, West Virginia?

7 **A.** No, I'm not aware of that.

8 **Q.** In your entire --

9 MR. ACKERMAN: One minute. I think I know where
10 we're going. I'm going to preserve our scope objection with
11 respect to questions regarding West Virginia because Mr.
12 Rannazzisi was not questioned regarding West Virginia in his
13 MDL deposition.

14 THE COURT: Okay.

15 MR. ACKERMAN: And that will be a standing
16 objection. I don't want to interrupt.

17 BY MS. WICHT:

18 **Q.** Now, Mr. Rannazzisi, during your entire tenure at
19 DEA, DEA never issued an Order to Show Cause against
20 Cardinal Health's Wheeling, West Virginia distribution
21 center; correct?

22 **A.** I, I don't know, but during my -- I don't know if they
23 ever received one or not. I think I would remember that,
24 but I'm not sure.

25 **Q.** During the time that you were at the Office of

1 Diversion Control from 2005 to 2015, it's fair to say you
2 would remember if you had issued an Order to Show Cause
3 against Cardinal Health's Wheeling, West Virginia
4 distribution center?

5 **A.** I think I would remember, yes.

6 **Q.** And you don't recall that; correct?

7 **A.** I don't recall that.

8 **Q.** And during the time that you were in the Office of
9 Diversion Control at DEA, DEA never issued an Immediate
10 Suspension Order against Cardinal Health's Wheeling, West
11 Virginia distribution center; correct?

12 **A.** I -- if they didn't get an Order to Show Cause served
13 on them, they wouldn't have an ISO.

14 **Q.** You discussed with Ms. Singer yesterday an enforcement
15 action that was taken against other Cardinal Health
16 distribution centers in late 2007. Do you recall that?

17 **A.** Yes.

18 **Q.** And that -- those enforcement actions issued against
19 distribution centers other than Wheeling, West Virginia
20 concerned distributions to what DEA contended were internet
21 pharmacies; is that right?

22 **A.** Yes. I'd have to go back and look at the Order to Show
23 Cause but, yes, I believe that's correct.

24 **Q.** All right. Now, at the time that DEA took action
25 against Cardinal Health in 2007, your office had possession

1 of Cardinal Health's ARCOS data going back years before
2 2007; correct?

3 **A.** I would hope so. Cardinal Health was required under
4 the Act to provide that ARCOS data.

5 **Q.** And Cardinal Health did provide that ARCOS data;
6 correct?

7 **A.** Yes, I guess, yes.

8 **Q.** You don't have any recollection --

9 **A.** I don't have any recollection that they didn't, but
10 they're required to under the Act under 827.

11 **Q.** And DEA used that ARCOS data to identify shipments that
12 DEA alleged were suspicious in the 2007 Orders to Show Cause
13 and ISOs; correct?

14 **A.** Retrospectively, yes, because they were not -- we
15 didn't have the suspicious orders.

16 **Q.** And enforcement action against Cardinal Health's
17 Lakeland, Florida distribution center in 2012 raised
18 allegations about Cardinal Health's distributions to four
19 specific pharmacies in Florida. Do you recall that?

20 **A.** I, I think I said I don't have the document, but if you
21 want me to look or if you have the Order to Show Cause
22 document or --

23 **Q.** That's okay. I'll move on from the specifics if you
24 don't recall and I'll just ask you this. At the time that
25 DEA took action against Cardinal Health in 2012, again your

1 office had possession of Cardinal Health's ARCOS data going
2 back years before that; correct?

3 **A.** Yes, we did. But, again, ARCOS, ARCOS data could only
4 be looked at retrospectively, months after transactions
5 occurred.

6 **Q.** And you used that ARCOS data to identify shipments that
7 DEA alleged were suspicious in the context of the Lakeland,
8 Florida Immediate Suspension Order; correct?

9 **A.** Yes, that is correct.

10 **Q.** And that ARCOS data that you used in 2007 and 2012 to
11 form the basis of the allegations in the enforcement action
12 also reflected every shipment of opioids by Cardinal Health
13 to every pharmacy in West Virginia; correct?

14 **A.** Yes, it should.

15 **Q.** And, obviously, that would include every pharmacy in
16 Cabell/Huntington; correct?

17 **A.** Again, it should, yes.

18 **Q.** Now, from the -- from 2012 until the time you left DEA
19 in 2015, DEA continued to receive ARCOS data reflecting
20 every shipment of every opioid by Cardinal Health to every
21 pharmacy in Cabell/Huntington; correct?

22 **A.** Again, according to 827, that's a requirement, so, yes.

23 **Q.** And you're not aware of Cardinal Health ever failing to
24 fulfill that requirement; correct?

25 **A.** I'm not aware of that.

1 **Q.** Now, during your tenure with the Office of Diversion
2 Control from July, 2005 to October of 2015, you never
3 instituted any enforcement proceedings against Cardinal
4 Health based on any shipment made to Cabell/Huntington, West
5 Virginia; correct?

6 **A.** I don't believe so.

7 **Q.** In your work at DEA, you never conducted any inspection
8 of Cardinal Health's Suspicious Order Monitoring System;
9 correct?

10 **A.** Me personally?

11 **Q.** You personally.

12 **A.** No.

13 **Q.** And you're familiar with a DEA employee name Kyle
14 Wright; correct? You've mentioned him a few times already.

15 **A.** Yes.

16 **Q.** He -- Mr. Wright reported to you?

17 **A.** He reported to his section chief who ultimately
18 reported to me, yes.

19 **Q.** Are you aware that Mr. Wright regularly communicated
20 with Cardinal Health between 2005 and 2007 about Cardinal
21 Health's efforts to address DEA's concerns about internet
22 pharmacies?

23 **A.** Well, he was in a section that would talk to not just
24 Cardinal Health, but other types of registrants.

25 **Q.** So you, you would expect him to have been talking to

1 Cardinal Health on that subject in that time frame; right?

2 **A.** I expected him to talk to a number of registrants, yes.

3 **Q.** Including Cardinal Health?

4 **A.** Yes.

5 **Q.** And are you aware that on April 26th, 2007, Kyle Wright
6 spoke with two of the Cardinal Health employees in charge of
7 anti-diversion and told them that he thought they were,
8 quote, doing the right things and heading in the right
9 direction?

10 **A.** I don't recall that specific -- I don't recall that,
11 no. Do you have the document or --

12 **Q.** I was just asking if you were aware of it, sir.

13 **A.** No, I don't believe I was aware of that.

14 **Q.** Now, you mentioned on your direct examination with Ms.
15 Singer someone named Barbara Boockholdt --

16 **A.** Boockholdt.

17 **Q.** I'm sorry -- who worked with you at DEA?

18 **A.** Yes.

19 **Q.** And she was the chief of the regulatory section at DEA
20 headquarters; is that correct?

21 **A.** Chief regulatory investigations, yes.

22 **Q.** And are you -- you're aware, are you not, that in 2009
23 DEA officials conducted a week-long visit at Cardinal
24 Health's headquarters in Ohio meeting with Mr. Michael Mone
25 and others to review Cardinal Health's improvements to its

1 Suspicious Order Monitoring System?

2 **A.** I recall that there was a team that went to Cardinal.
3 I don't recall who exactly was on that team or when it
4 happened. But, yeah, I recall there was a meeting.

5 **Q.** And are you aware that Ms. Barbara Boockholdt attended
6 that meeting from DEA headquarters?

7 **A.** If it was a regulatory meeting, there's a good
8 possibility that she would have attended that meeting.

9 **Q.** But you did not attend the meeting; correct?

10 **A.** I did not attend that meeting.

11 **Q.** So you don't know what DEA said to Cardinal Health
12 about Cardinal Health's Suspicious Order Monitoring System
13 in that meeting; correct?

14 **A.** I do not.

15 **Q.** After you left DEA, are you aware of the fact that
16 there were meetings between Mr. Todd Cameron, the head of
17 Anti-Diversion at Cardinal Health, and officials at DEA
18 headquarters to talk about Cardinal Health's Suspicious
19 Order Monitoring System?

20 **A.** It would be after I left, so, no.

21 **Q.** You're not aware of those -- how many meetings
22 occurred?

23 **A.** No.

24 **Q.** Obviously, you didn't attend?

25 **A.** Not after I left, no.

1 **Q.** Before you left DEA, had you invited Mr. Cameron in to,
2 to DEA to discuss Cardinal Health's system?

3 **A.** I never invited Todd Cameron -- is it Todd Cameron?
4 Yeah. No.

5 **Q.** So do you have -- so you never received -- it's fair to
6 say you never received any information or briefing on
7 Cardinal Health's Suspicious Order Monitoring System post
8 2012; correct?

9 **A.** The last briefing I received was before I was going to
10 testify in the TRO hearing in Washington, D.C.

11 **Q.** And that would have been in 2012 sometime?

12 **A.** That would have been, yeah, probably February --
13 February of 2012 sometime, February or March of 2012.

14 **Q.** And after that point in time, after that briefing, you
15 have no knowledge about what Cardinal Health's Suspicious
16 Order Monitoring System, how it operated; correct?

17 **A.** After that time, no.

18 MS. WICHT: May I have a moment to confer, Your
19 Honor?

20 THE COURT: Yes.

21 (Pause)

22 MS. WICHT: That's all I have. Thank you very
23 much.

24 MR. NICHOLAS: Yes, Your Honor, I do have some
25 questions.

1 THE COURT: Go ahead.

2 CROSS EXAMINATION

3 BY MR. NICHOLAS:

4 Q. Good afternoon, Mr. Rannazzisi. How are you?

5 A. Fine.

6 Q. You and I, we met once before on Zoom?

7 A. Yes, we did.

8 Q. Do you remember that?

9 A. I do remember that.

10 Q. Good. It's not the most satisfactory way to meet
11 people but, you know, --

12 A. It's nice meeting you in person.

13 Q. Same here.

14 A. Of course under these circumstances.

15 Q. Yeah, right. And I will say as we get set up
16 technically that I have a tremendous misfortune of being --
17 of having my examination begin at 4:25 in the afternoon on a
18 long Wednesday, so I apologize for that.

19 I want to apologize to the Court in advance in case I
20 can't finish today. It's just one of those things. I'm not
21 going to be that long, but I'm not sure I can get done by
22 5:00. So please forgive me in advance.

23 A. Actually, this was the same circumstance we were under
24 the last time.

25 Q. You know, you're absolutely right. You have a good

1 memory.

2 Okay. I guess I'll just begin by asking you this
3 question. You have testified both yesterday and today that
4 at least during your time at, you know, in your supervisory
5 position between 2005 and 2015, the DEA did not approve
6 Suspicious Order Monitoring Systems that were developed by
7 distributors; is that correct?

8 **A.** That is correct.

9 **Q.** Okay. And is it your testimony that the DEA did not
10 approve such systems before your tenure?

11 **A.** DEA -- the policy that was in place before my tenure
12 was the same policy -- I'm testifying from 2005 to 2015.
13 But I was told that that was the policy when I got to the
14 Office of Diversion Control in -- actually, in 2004 when I
15 originally got to the Office of Diversion Control, that was
16 the policy.

17 **Q.** You say you were told. Was there a written policy that
18 so stated or are you just telling us what your recollection
19 is of what you were told?

20 **A.** I'm telling you my recollection. I had briefings on
21 any number of topics and I was -- when we came into that,
22 that distributor initiative briefing when I started asking
23 questions about suspicious order monitoring, they said that
24 the Suspicious Order Monitoring Systems were up to the
25 companies. And we would not intervene, or we would not tell

1 them how to file them and they directed me to 1301.74(b) .
2 Actually, that was the first time I actually looked at
3 1301.74(b) .

4 **Q.** Were you aware that the DEA had approved a Suspicious
5 Order Monitoring System developed by AmerisourceBergen
6 between 1996 and 1998?

7 **A.** No.

8 **Q.** Okay.

9 MR. NICHOLAS: Ritchie, can we cull up AM-WV-0258?
10 And let's hand it out.

11 May I approach, Your Honor?

12 THE COURT: Yes.

13 BY MR. NICHOLAS:

14 **Q.** Do you recognize this document?

15 **A.** Yes, I've seen this document before.

16 **Q.** Is it an approval from the DEA of AmerisourceBergen's
17 Suspicious Order Monitoring System as of 1998?

18 **A.** I believe there's a request letter that goes along with
19 this. So this letter says, "We're granting approval to your
20 request to implement on a nationwide basis your newly
21 developed system to identify and report suspicious orders
22 for controlled substances and regulated chemicals as
23 required by federal regulations."

24 But I believe there's another letter that discusses
25 what the approval actually -- what the request for approval

1 is.

2 **Q.** Well, there's a series of letters and we will go
3 through them. But right now I'm asking you to look at this
4 letter and tell me whether it is an approval of
5 AmerisourceBergen's newly developed system to identify and
6 report suspicious orders for controlled substances and
7 regulated chemicals as required by federal regulation.

8 **A.** That's what this letter says, yes. But --

9 **Q.** Okay.

10 **A.** -- I'd like to see the request letter that's attached
11 to it.

12 **Q.** We will get to that. We will get to the
13 correspondence. But looking at this letter -- well, let's
14 back up. The letter is written to Chris Zimmerman, the
15 Director of Regulatory Compliance and Security Services for
16 Bergen Brunswig Corporation. Do you see that?

17 **A.** Yes.

18 **Q.** Okay. And Bergen Brunswig is the predecessor of
19 AmerisourceBergen; correct?

20 **A.** Yes.

21 **Q.** Okay. And the letter is written on U.S. Department of
22 Justice letterhead; correct?

23 **A.** That's correct.

24 **Q.** And it says "Drug Enforcement Administration" under
25 that; right?

1 **A.** Yes.

2 **Q.** And it's dated July 23rd, 1998; correct?

3 **A.** Yes.

4 **Q.** Okay. Now, it's signed by Patricia M. Good. Do you
5 see that?

6 **A.** Yes.

7 **Q.** And she was the Chief Liaison and Policy Section,
8 Office of Diversion Control. Do you see that?

9 **A.** Yes.

10 **Q.** Now, I also want to ask you about the cc's because this
11 was cc'd to DPMs. Let's start with DPMs.

12 **A.** Yes.

13 **Q.** Does that stand for Diversion Program Managers?

14 **A.** Yes.

15 **Q.** Okay. How many Diversion Program Managers were there
16 in 1998?

17 **A.** I, I don't know how many there were in 1998.

18 **Q.** Can you give me a ball -- can you ballpark it?

19 **A.** Well, there's 21 field divisions. I'd guess there
20 would be about half, so probably, maybe 10 or 11.

21 **Q.** So this was cc'd to 10 or 11 Diversion Program,
22 Diversion Program Managers; correct?

23 **A.** That's correct.

24 **Q.** All right. What does OD/D stand for? Is it Office of
25 Diversion Control?

1 **A.** Yeah. I believe -- and, again, this is way before my
2 time. But I believe that was designated for the Office of
3 the Deputy Director.

4 **Q.** Okay. It was also cc'd to ODX. What's ODX?

5 **A.** That would be the executive assistant to the deputy
6 assistant administrator.

7 **Q.** Okay. And if you see at the bottom it says "Subject:
8 Approve Suspicious Order Monitoring System." Do you see
9 that?

10 **A.** Yes, I see that.

11 **Q.** Is there anything about this letter that would lead
12 anyone to a conclusion other than that as of July 23rd,
13 1998, the DEA had approved Bergen Brunswig's newly developed
14 system to identify and report suspicious orders for
15 controlled substances and regulated chemicals as required by
16 federal regulation?

17 THE COURT: Mr. Ackerman.

18 MR. ACKERMAN: Objection, speculation, foundation,
19 calling for an opinion.

20 THE COURT: Overruled. The question was: Is
21 there anything about this letter that would -- I think he
22 can answer that.

23 THE WITNESS: When I look at a letter like this, I
24 would like to review what the actual request was before
25 because I know it says "Subject: Approve Suspicious Order

1 Monitoring System." But, quite frankly, I don't -- I've
2 never seen this, this -- the bottom of the thing with the
3 cc's, usually that's on a separate, a separate paper
4 separated from the actual correspondence.

5 So I'm just -- I'm not saying this is wrong, but I'm
6 just -- I -- before I comment on it, I'd like to see what
7 you're actually request, requesting from DEA before you get,
8 you know, my response because I don't know. I mean, I
9 wasn't there in 1998 and I don't know exactly what you
10 requested from DEA.

11 BY MR. NICHOLAS:

12 **Q.** All right. Well, just so, just so there's no
13 uncertainty on the record, this document and this
14 version of this document was produced by the DEA from
15 their files.

16 **A.** Okay.

17 **Q.** So if you're, if you're suggesting there was something
18 improper about it --

19 **A.** Absolutely -- I'm not suggesting anything. I just --
20 generally, when this cc is written like this, it's on a
21 separate page. That's all I'm saying. And that's why I
22 just didn't -- I just -- I've never seen it set up like
23 this. But, then again, this was 1998.

24 **Q.** It was 1998.

25 **A.** So -- but, again, I just can't give you an answer

1 without seeing what the actual request was.

2 **Q.** Well, on its face, it's an approval; correct?

3 **A.** On its face, it looks like an approval.

4 **Q.** And when it was cc'd --

5 THE COURT: Mr. Farrell.

6 MR. FARRELL: Objection. We're going to repeat
7 the foundation objection. This witness has said he wasn't
8 there. And to be fair to both sides, this document was
9 discussed at length in the Prevoznik deposition through a
10 30(b)(6) witness proffered by the DEA.

11 MR. NICHOLAS: I don't know what relevance that
12 has to this.

13 THE COURT: Well, I think you need to move on. I
14 think you're kind of beating this into the ground, Mr.
15 Nicholas.

16 MR. NICHOLAS: Okay. I certainly don't want to
17 beat anything into the ground.

18 BY MR. NICHOLAS:

19 **Q.** So why don't we go to the correspondence that
20 preceded this approval between -- that occurred between
21 1996 and 1998. And let's start with -- let's go to
22 exhibit AM-WV-00781, please.

23 And what I'm handing out is another, is another copy of
24 the approval letter. But attached to this exhibit is a
25 series of correspondence that I will ask you about. And

1 this is the correspondence that you were asking me about,
2 Mr. Rannazzisi.

3 MR. NICHOLAS: May I approach, Your Honor?

4 THE COURT: Yes.

5 THE WITNESS: Thank you very much.

6 MR. FARRELL: Without belaboring the point, again,
7 objection to the foundation with this witness with this
8 series of documents. The record is going to have much more
9 detail from other witnesses with direct knowledge including
10 the DEA.

11 THE COURT: Well, I think this is
12 cross-examination and I think Mr. Nicholas can use this as a
13 basis to conduct his cross to a certain extent.

14 So go ahead, Mr. Nicholas. I overrule the objection.

15 MR. NICHOLAS: Thank you, Your Honor.

16 BY MR. NICHOLAS:

17 Q. Let's start with, let's start with -- first of all,
18 just for the record, this is -- this document is already
19 admitted in evidence, as was the prior document.

20 So moving on from there, if you will turn to Page 00009
21 which is the September 30th, 1996, letter to Mr. Thomas
22 Gitchel. We can start with that. Tell me when you're
23 there.

24 A. To Thomas Gitchel?

25 Q. Yes.

1 **A.** December 30th did you say?

2 **Q.** September 30th.

3 **A.** Okay. I got it.

4 **Q.** And if you look at the first -- well, this letter is
5 dated September 30th. It's to Mr. Thomas Gitchel who as of
6 that date was the Chief Liaison and Policy Section, Drug
7 Enforcement Administration, United States Department of
8 Justice. So he was Patricia Good's predecessor; correct?

9 **A.** That is correct.

10 **Q.** Okay. And the letter was sent by Chris Zimmerman from
11 AmerisourceBergen; correct?

12 **A.** Yes.

13 **Q.** And Chris Zimmerman was the manager of corporate
14 security -- I'm sorry -- for Bergen Brunswig at that time;
15 correct?

16 **A.** Yes.

17 **Q.** And Mr. Zimmerman begins his letter by saying, "The
18 purpose of this letter is to introduce the Drug Enforcement
19 Administration, DEA, to an innovative new system under
20 development by Bergen Brunswig Drug Corporation, BBDC, to
21 monitor and report suspicious orders of controlled
22 substances which fit the suspicious order criteria outlined
23 in 21, C.F.R., Section 1301.74(b)."

24 Do you see that?

25 **A.** Yes.

1 **Q.** So this was AmerisourceBergen -- this was Bergen
2 Brunswick's initiative. This was not initiated by the DEA.
3 Right?

4 **A.** It appears that way, yes.

5 **Q.** And the next sentence that begins the next paragraph
6 says, "By way of background, as you know, BBDC participated
7 in the development of a model excessive purchase report now
8 in use by many distributor registrants."

9 Do you see that?

10 **A.** Yes.

11 **Q.** Okay. And if you go to the -- if you go to the last
12 sentence of the paragraph, it says, "The report is produced
13 in hard copy form monthly and is sent via certified mail to
14 each DEA field office having responsibility for the
15 reporting BBDC locations."

16 Do you see that?

17 **A.** Yes.

18 **Q.** Now, you had spoken in your direct examination about
19 the fact -- and you kind of -- you were describing it as
20 something you were unhappy with, about the fact that these
21 reports only came monthly to you. Do you recall that
22 testimony, that they didn't come in real-time?

23 **A.** Well, they weren't suspicious order reports. They were
24 excessive purchase reports.

25 **Q.** Well, we'll get to that. That's, that's your view. I

1 understand that. But you also were saying that the
2 excessive -- even if you call them excessive purchase
3 reports, they weren't coming timely. They were coming only
4 monthly. Do you recall that?

5 MR. ACKERMAN: Objection. I think that misstates
6 his testimony.

7 THE WITNESS: I think what I said was --

8 THE COURT: Just a minute.

9 THE WITNESS: I'm sorry, Your Honor. I'm sorry.

10 THE COURT: I'm not sure -- overruled. Go ahead.

11 THE WITNESS: Yeah. I think what I said was these
12 excessive purchase reports that came monthly are not
13 suspicious order reports and they really have little value.
14 That's what I said. I'm pretty sure I said that.

15 BY MR. NICHOLAS:

16 **Q.** If you go to the next paragraph, Mr. Zimmerman
17 writes to Mr. Gitchel. "While feedback from different
18 DEA users over the years has generally confirmed our
19 belief that this report, standing alone, is a useful law
20 enforcement tool, BBDC's suspicious order compliance
21 program also involves the telephonic reporting of
22 customer orders to DEA. In an average year, BBDC logs
23 over 12,000 telephone calls to DEA field offices
24 nationwide." And then it goes on.

25 Do you see that?

1 **A.** Yes.

2 **Q.** Okay. And if you turn to the next page, Mr.
3 Rannazzisi, and go to the middle of the page, there's a
4 paragraph that begins "against." And it says, "Against this
5 backdrop, BBDC set to work on the development of a
6 suspicious order reporting program that would provide better
7 quality information to DEA in a more efficient manner."

8 Do you see that?

9 **A.** Yes.

10 **Q.** So Bergen Brunswig was -- wanted to, wanted to develop
11 a suspicious order reporting program that would provide
12 better information to the DEA; correct?

13 MR. FARRELL: Objection, foundation, speculation.

14 THE COURT: Well, the letter itself speaks to that
15 point, doesn't it, Mr. Nicholas?

16 MR. NICHOLAS: It does. I'm really responding to
17 the fact that Mr. Rannazzisi in his direct testimony has
18 suggested time and time again that the distributors did not
19 do anything to provide information that was useful to the
20 DEA. This goes square dead on directly to that, or I feel I
21 have to at least show the witness.

22 MR. ACKERMAN: The concern we have, Your Honor, --

23 THE COURT: Well, this is cross-examination. I
24 think this is proper. And for the reasons Mr. Nicholas just
25 said, I'll allow it.

1 BY MR. NICHOLAS:

2 **Q.** Now, Mr. Rannazzisi, I, I'm mindful of what the
3 Judge just said which is that the letter largely speaks
4 for itself, and it does. But -- so if you look at the
5 next paragraph, I will, I will spare everyone in the
6 courtroom my reading of the paragraph.

7 But if you look at it, you can see -- tell me if you
8 agree that, that Bergen Brunswig is proposing, you know, to
9 provide substantive information that it believes will be
10 more useful to the DEA than it has been provided previously.

11 And it makes reference to an average of the customer's
12 prior four months of orders, customers whose orders exceed
13 by a specific percentage their prior four-month average
14 order history would be printed on a summary report.

15 It says at the end of the paragraph -- here I am
16 reading it -- the summary report would show the customer
17 name, address, DEA number, item description, NDC number,
18 order date, active ingredient volume ordered, active
19 ingredient shipped, and customer allowance.

20 So AmerisourceBergen -- so Bergen Brunswig is proposing
21 to create a program that would provide all of that
22 information to the DEA. Correct?

23 **A.** That's what the letter says, yes.

24 **Q.** Okay. And the letter also, also talks about the manner
25 of transmission and the timing of transmission on the last

1 page where it says, "Our intent is to receive DEA's
2 permission to replace our current manner of daily suspicious
3 order reporting, e.g. U.S. mail and telephone calls, with
4 this daily electronic facsimile report."

5 And then it says, "We would like to have DEA input on
6 the final product because DEA will be the primary users.
7 Our suggestion would be to coordinate with one of your field
8 offices, perhaps the Los Angeles office, to meet with our
9 project development team."

10 Do you see that?

11 **A.** Yes.

12 **Q.** And it proposes beta testing to be done in connection
13 with the Los Angeles office, the DEA's Los Angeles office;
14 correct?

15 **A.** Yes.

16 **Q.** Okay. So that's, that's the opening -- that's the
17 first thing that was written on this subject and it was from
18 Mr. Zimmerman to Mr. Gitchel.

19 Now, let's turn to, let's turn to Mr. Gitchel's
20 response which is dated October 29th, 1996. It's the next
21 letter in the chain. And it's written to Mr. Chris
22 Zimmerman and it's signed by Thomas Gitchel of the DEA. And
23 it refers to Mr. Zimmerman's letter to him.

24 And, Ritchie, can you just highlight the first sentence
25 of the second paragraph, please? Can you pull that out?

1 Now, it begins, "We have reviewed your proposal."

2 **A.** Yeah.

3 **Q.** The first sentence: "We have reviewed your proposal
4 and feel it to be a viable alternative to the current
5 system."

6 Do you see that?

7 **A.** Yes.

8 **Q.** All right. So let's go down to the next paragraph
9 which says, "We note that," and just pull the whole
10 paragraph out.

11 And you can see here by this paragraph that Mr. Gitchel
12 is engaging in the substance of the proposal; correct?

13 **A.** Well, the original request, the original request is to
14 receive permission to replace current matter of daily
15 suspicious reporting via U.S. mail or telephone calls with
16 an electronic facsimile report. That's the request that was
17 in this original email.

18 **Q.** Well, I'm not going to argue with you about what the
19 original letter says and doesn't say, other than to remind
20 you, Mr. Rannazzisi, that there was an extensive description
21 of the kind of substantive information that Bergen Brunswick
22 proposed to provide to the DEA. You recall that; right?

23 **A.** Well, it was laid out. But the only request that's in
24 that email, or in that letter is a facsimile -- use of
25 facsimile rather than telephone call or mail. And, and that

1 is the type of request that would, actually can be approved
2 because it's just a change of reporting.

3 **Q.** Well, --

4 **A.** So --

5 **Q.** So your testimony is that over this two-year period of
6 back and forth --

7 **A.** Uh-huh.

8 **Q.** -- between Bergen Brunswig and the DEA, the beta
9 testing, the substantive discussions, the testing at various
10 sites, that all of that only had to do with whether
11 information would be faxed as opposed to mailed. Is that
12 your testimony?

13 **MR. FARRELL:** Objection, Your Honor. Again,
14 foundation. He wasn't there. He doesn't have direct
15 knowledge. And there's extensive testimony of people with
16 knowledge other places in the record.

17 **THE COURT:** Well, he can ask him about it. And if
18 he doesn't know anything about it, he can say he doesn't
19 know anything about it.

20 Go ahead, Mr. Nicholas.

21 **BY MR. NICHOLAS:**

22 **Q.** Do you know anything about it?

23 **A.** I was not there during this time period. But I can
24 only go with the letters you gave me. And these letters --
25 this first one is a request for a change in the way that the

1 transmission of the suspicious order to the DEA offices.

2 And, yes, they would have to beta test that and it
3 would go to multiple offices. And it takes time to beta
4 test it. So I'm just saying that's what it says. I was not
5 in headquarters at the time and I can't tell you exactly
6 what they were doing.

7 MR. NICHOLAS: Ritchie, can we go back to the
8 first exhibit that we looked at, AM-WV-02658.

9 BY MR. NICHOLAS:

10 Q. The first sentence says, "This is to grant approval
11 of your request to implement on a nationwide basis your
12 newly developed system to identify and report suspicious
13 orders."

14 Do you see that?

15 A. Yes, I do.

16 Q. So it uses the word "identify." It separates it with
17 an "and." And then it says "and report." Do you see that?

18 A. Yes.

19 Q. Okay.

20 A. You know, just if I may, you have two of the exact same
21 letter and these letters are totally different, even though
22 they're exactly the same.

23 One is -- it looks like -- it looks like they're the
24 same dates. They're the same "to" and "from." They're the
25 same content. But it looks like they're totally different.

1 One's got the chopped sheet on the bottom. One doesn't have
2 a chop sheet. One has Patricia Good's name on the top -- on
3 the bottom and the other one has it underneath the
4 "sincerely." These are the same letters, the same exact
5 letters but two different copies.

6 **Q.** What are you suggesting?

7 **A.** Well, I -- because this one doesn't have this
8 underneath -- I'm not suggesting anything. They're the
9 exact same letters.

10 **Q.** Yeah.

11 **A.** So you're asking me to testify about something I -- I
12 wasn't in headquarters at the time, but I've been in
13 headquarters long enough to see differences in the exact
14 same memo. And I don't -- it looks like they're two
15 different memos for the exact same thing on the same date.

16 **Q.** Are you suggesting anything improper?

17 **A.** I'm not suggesting anything --

18 THE COURT: He's saying he doesn't know anything
19 about them.

20 MR. NICHOLAS: Okay. That's fine.

21 BY MR. NICHOLAS:

22 **Q.** Let me ask you this, Mr. Rannazzisi.

23 Did you ever come to understand when you took your --
24 when you, when you became -- when you took over Diversion
25 Control in 2005, were you made aware of the fact that this

1 approval was sitting out there that had been issued to
2 Bergen Brunswig in 1998?

3 **A.** No, I was not.

4 **Q.** No one ever told you about it?

5 **A.** No. When I got to headquarters, they told me -- what I
6 testified to was we don't approve Suspicious Order
7 Monitoring Systems. That's what I was briefed on.

8 When we went into the distributor initiative -- the
9 distributor initiative briefings, I understood that was part
10 of the distributor initiative briefings, and we talked about
11 that. It was in the letters. It was -- I mean, that's -- I
12 can only go on my briefings.

13 I wasn't there in 1998. I don't know what they did in
14 1998. But when I was there, I was briefed by very competent
15 staff who knew exactly what they were doing. And I was
16 briefed on Suspicious Order Monitoring Systems. That's how
17 I could go in and, and evaluate what they were doing to make
18 a determination how they were doing it and if they're doing
19 it appropriately.

20 **Q.** Did you ever talk to Patricia Good about this approval
21 letter?

22 **A.** No.

23 **Q.** Did you ever talk to Thomas Gitchel about this approval
24 letter?

25 **A.** Thomas Gitchel was retired when I got there, and Pat

1 Good was about ready to retire when I got there.

2 **Q.** Did you ever talk to Mr. Zimmerman about the approval
3 letter?

4 **A.** No, I did not. Again, I want to tell you I'm not, I'm
5 not accusing you or anything. But I, I'm trained when I
6 look at documents like this, especially DEA documents, we're
7 trained to look at them to ensure. So I don't know why
8 there's two different ones, but I'm not accusing you of
9 anything. I wouldn't expect that you would do anything like
10 that.

11 **Q.** No, I --

12 **A.** I'm just saying they're the same documents but they're
13 two different -- it's the same document, just two different
14 set-ups.

15 **Q.** All right. I understand. I appreciate that.

16 Let's go to P-000032, 032.

17 MR. NICHOLAS: And, Ritchie, if we could go to
18 Page 3 of that document and highlight the last sentence of
19 the -- the last sentence of the second paragraph which
20 begins with the word "past communications."

21 BY MR. NICHOLAS:

22 **Q.** Now, this is your December 27th, 2007, letter to
23 all the manufacturers and distributors; correct?

24 **A.** Yes, sir.

25 **Q.** And it wasn't directed to -- it wasn't a letter

1 specific to anyone. It was just a general letter to the
2 industry. Right?

3 **A.** Yes, sir.

4 **Q.** Okay. And this sentence says, "Past communications
5 with DEA, whether implicit or explicit, that could be
6 construed as approval of a particular system for reporting
7 suspicious orders, should no longer be taken to mean that
8 DEA approves a specific system."

9 Do you see that?

10 **A.** Yes.

11 **Q.** Okay. Prior to and other than this statement by you in
12 this letter, are you aware of any writing that was ever
13 directed to AmerisourceBergen that said, "Your prior
14 approval is no longer valid"?

15 **A.** I, I don't recall any type of correspondence
16 specifically to AmerisourceBergen, no. But -- and I've got
17 to go back and look, but I believe that was part of the 2005
18 distributor initiative. I don't have it handy, but --

19 **Q.** Well, right now I'm just asking you if anything --
20 you're aware of any writing that was issued under your --
21 while you were on your watch, for example, that was sent to
22 AmerisourceBergen withdrawing approval of this, of this
23 program?

24 **A.** I don't know of any, any type of correspondence that
25 was sent specifically to AmerisourceBergen withdrawing that

1 program because I didn't know that program was approved, and
2 I still don't. I'm not saying -- I just don't have any
3 information because I was not back in headquarters in 1998.
4 So I don't know if it was approved or not.

5 **Q.** So is it fair to say that as far as you personally
6 know, this correspondence from you in December of 2007 would
7 have been the first time that AmerisourceBergen was notified
8 in writing that its prior approved program was no longer an
9 approved program?

10 **A.** That letter --

11 MR. SINGER: Objection, Your Honor. This is
12 contrary to the testimony here. Mr. Rannazzisi has
13 testified that he didn't know that this was an approved
14 program, and that it was policy not to approve programs. So
15 I think the question mischaracterizes the testimony and it's
16 misleading.

17 THE COURT: Well, the question was whether he knew
18 of any prior notification that any program had not been
19 approved. And that's a simple question. You can answer
20 that.

21 THE WITNESS: And I don't know. I didn't know any
22 program was approved. And, no, I don't know any program
23 that -- you know, we didn't send any correspondence
24 disapproving a program.

25 **Q.** Okay.

1 MR. NICHOLAS: I think we could probably -- I, I
2 have more to do. It's a good time for a break if it's all
3 right with the Court.

4 THE COURT: I assume you have more to go in the
5 morning.

6 MR. NICHOLAS: I do.

7 THE COURT: And, Ms. Singer, you're going to have
8 some redirect?

9 MS. SINGER: I expect it to be very brief, Your
10 Honor.

11 THE COURT: Well --

12 MR. NICHOLAS: Do you want me to keep going?

13 THE COURT: How long do you think it will take?

14 MR. NICHOLAS: 20 minutes, you know. I feel bad,
15 you know.

16 THE COURT: These things happen.

17 And you're going to have some redirect, Ms. Singer?

18 MR. SINGER: I expect to have some redirect. I
19 will try to keep it brief, Your Honor, but probably about
20 half an hour.

21 THE COURT: Okay.

22 Mr. Rannazzisi, it's probably cruel and unusual
23 punishment, but I'm going to ask you to come back at 9:00 in
24 the morning, sir, and we'll try to get you out of here
25 sometime tomorrow morning.

1 THE WITNESS: I'm more than happy to, Judge.
2 Thank you.

3 THE COURT: All right.

4 Ms. Singer, you're on your feet. Do you want to say
5 something?

6 MR. SINGER: I just figured it would be more
7 efficient. It seems we're moving towards a recess.

8 THE COURT: Well, I have no idea where this is
9 going to go from here and I think, I think we'll recess
10 until tomorrow morning at 9:00. I previously told you how
11 unreliable I think lawyers can be and how much time they're
12 going to take. I hesitate to go down this path. We'll see
13 everybody in the morning.

14 (Trial recessed at 4:58 p.m.)

15
16 CERTIFICATION:

17 I, Ayme A. Cochran, Official Court Reporter,
18 and I, Lisa A. Cook, Official Court Reporter, certify that
19 the foregoing is a correct transcript from the record of
20 proceedings in the matter of The City of Huntington, et al.,
21 Plaintiffs vs. AmerisourceBergen Drug Corporation, et al.,
22 Defendants, Civil Action No. 3:17-cv-01362 and Civil Action
23 No. 3:17-cv-01665, as reported on June 9, 2021.

24

25 S\Ayme A. Cochran

s\Lisa A. Cook

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